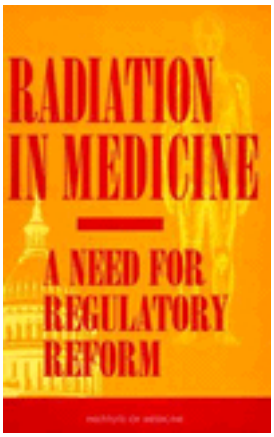

Radiation in Medicine: A Need for Regulatory Reform

Kate-Louise D. Gottfried and Gary Penn, Editors; Committee for Review and Evaluation of the Medical Use Program of the Nuclear Regulatory Commission, Institute of Medicine

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RADIATION IN MEDICINE

A NEED FOR REGULATORY REFORM

Committee for Review and Evaluation of the Medical Use Program
of the Nuclear Regulatory Commission

Kate-Louise D. Gottfried and Gary Penn, Editors

Division of Health Care Services
INSTITUTE OF MEDICINE

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NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under both the Academy's 1863 congressional charter responsibility to be an adviser to the federal government and its own initiative in identifying issues of medical care, research, and education. Dr. Kenneth I. Shine is president of the Institute of Medicine.

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The image adopted as a logotype by the Institute of Medicine is based on a relief carving from ancient Greece, now held by the Staatlichemuseen in Berlin.

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Preface

Three events played an important role in prompting this study: a November 1992 radiation incident in Indiana, Pennsylvania; a December 1992 week-long series of articles in the Cleveland *Plain Dealer* on the hazards of radiation medicine; and a May 1993 congressional hearing, chaired by Senator John Glenn, on the regulation of radiation medicine. During the summer of 1993, following these events, the U.S. Nuclear Regulatory Commission (NRC) negotiated with the Institute of Medicine (IOM) of the National Academy of Sciences to undertake an independent review and evaluation of the NRC's Medical Use Program, which oversees the regulation of reactor-generated byproduct material. The review was intended to complement an internal management review already under way within the NRC.

As a result, the IOM formed the Committee for Review and Evaluation of the Medical Use Program of the Nuclear Regulatory Commission, which officially commenced a two-year study on January 2, 1994. The study was conducted by a 16-member committee of experts from a broad spectrum of disciplines, including medicine (diagnostic radiology, nuclear medicine, radiation oncology, and nuclear cardiology), health physics, economics, quality of care, biostatistics, public health, nursing, law, ethics, and regulatory matters and public policy analysis.

The NRC's charge to the committee specifically requested a review of the NRC's Medical Use Program, an evaluation of the program's adequacy, and recommendations for changes. Through the IOM study, the NRC sought an evaluation of whether the rules, policies, and procedures of the current regulatory framework for medical uses of byproduct material fulfill the NRC's statutory responsibilities for public health and safety. There is particular interest

in regulating the medical uses of nuclear reactor-generated byproduct material not only because byproduct material is a source of ionizing radiation, which, unlike nonionizing radiation, poses health and safety risks, but also because of nuclear reactors' special history and ties to weaponry. There are, however, sources of ionizing radiation other than byproducts that are also widely used in medicine. During the course of this study, in fact, the committee realized that procedures involving byproduct material represent only one-tenth of all medical applications of ionizing radiation. In this connection, the NRC specifically requested recommendations on a uniform national approach to regulation of the entire field of ionizing radiation in medicine, including all sources, not solely byproduct material.

The committee first examined the scientific foundation for the use of ionizing radiation in medicine, including the scientific debate concerning its risks. It then discussed the appropriate level and scope of regulation for using ionizing radiation in medicine. The committee strove to clarify key issues, to define potential alternatives for regulatory programs, and to achieve a consensus as to recommendations. Its deliberations and fact-finding efforts included site visits, commissioned papers, a public hearing, the convening of a technical panel, attendance at professional conferences, and several committee meetings.

The result of the committee's study is this report. In it, the committee proposes a major shift in the elaborate regulatory structure that has developed over the five decades since byproducts were first used for peaceful purposes. Nearly all of the committee agreed on the findings, conclusions, and recommendations in the report. Unlike most National Research Council committees, however, this committee did not reach total unanimity on the final recommendations. The separate statement of one committee member's views is included in Appendix L. The report, which was reviewed under the procedures of the National Research Council, constitutes the committee's final statement.

As chairman, I wish to express my sincere appreciation to the IOM staff, particularly Kate-Louise Gottfried, and all members of the committee, for their diligence, sensitivity, and commitment to this process. I also wish to express my gratitude to all those who assisted us in providing information during our deliberations. The recommendations that we are proposing reflect the expertise and knowledge of a diverse group of professionals.

Charles E. Putman, M.D.
Chair

Acknowledgments

This report is the result of the considered deliberations of the Institute of Medicine (IOM) Committee for Review and Evaluation of the Medical Use Program of the Nuclear Regulatory Commission. The conclusions and recommendations reflect the judgments of the committee. Generous support for this study was provided by the Nuclear Regulatory Commission (NRC, Contract No. NRC-02-94-002).

This report is the result of extensive collective efforts among the committee members, staff, and a variety of other contributors. The committee worked diligently writing and rewriting major sections of this report. There were many other contributors to this truly collaborative process, however, and the committee wishes to express its gratitude to them.

The NRC respected the IOM's autonomy and stood ready to provide whatever information or assistance was needed. Under the leadership of Patricia Rathbun, the NRC contract officer, the IOM committee and staff were briefed and provided with documents, conducted conference calls, and obtained other important information from the NRC, all in a timely manner. Robert Bernero, Carl Papierello, Myron Pollycove, Don Cool, and John Glenn, to name a few, and a number of NRC staff were eager to provide assistance in whatever way possible. Chairman Selin and Commissioners Rogers and de Planque each visited one of our committee meetings and shared their candid views and concerns with the committee.

A variety of guests were also invited to our committee meetings to provide their unique perspectives on relevant study issues. Charles Meinhold, President of the National Council of Radiation Protection and Measurements, addressed the committee. Barry Siegel of the NRC's Advisory Committee on the Medical

Uses of Radioisotopes (ACMUI) gave a presentation in his capacity as ACMUI Chair. Robert Alvarez, former professional staffer on the Senate Committee for Governmental Affairs, who worked closely with Senator John Glenn, provided both critical congressional and non-regulated community perspective for the committee's consideration.

Representatives of the NRC, the Food and Drug Administration (FDA), and the regulated community also shared their views with the committee. Richard Bangart, Director of State Programs of the NRC, discussed the existing state program system, its strengths and weaknesses. James Lieberman, Director of the NRC's Office of Enforcement, explained the basics of the enforcement process. Stuart A. Treby, Assistant General Counsel for Rulemaking and Fuel Cycle in the Office of the NRC General Counsel, provided an important perspective on the NRC's rulemaking process and authority. Representatives from the FDA described their agency's role in areas subject to investigation by the committee. Among them were D. Bruce Burlington, Marvin Rosenstein, Richard E. Gross, and James Cheever, who gave generously of their time to meet with and answer questions from the committee. Elizabeth Jacobson, Joseph Leavitt, and Bob Eccleston also were gracious in providing information about the FDA. Practicing physicians who visited the committee and shared their experiences with the use of radionuclides included Mike Hattwick, Worth B. Daniels, Richard Rubin, Lynn Campbell, Louis Harrison, and Daniel Clarke. Dwight Glenn also provided perspective from the physicists' vantage point.

Various individuals from the Conference of Radiation Control Program Directors (CRCPD), including Charles Hardin, President, and Wayne Kerr, from the Illinois State Radiation office, provided valuable input and assistance throughout the study process. Terry Devine and staff at the main CRCPD office provided basic information, data, and reference documents and were unfailingly helpful. Joel Nobel and his staff at the ECRI also generously provided data. The committee also appreciated Carol Marcus's efforts to keep it apprised of documents and information circulating throughout the nuclear medicine community. Finally, Jerome A. Halperin, of the United States Pharmacopeial Convention, Inc., provided a context for understanding the history and handling of radiopharmaceuticals.

Site visits were conducted often during the study process to provide the committee with firsthand information. This activity enabled committee members who were less familiar with the day-to-day processes involved in radiation medicine to meet with professionals in a clinical setting and interact with a variety of individuals involved in this aspect of medicine. Owing to confidentiality requirements, specific individuals and institutions cannot be named, but the committee is indebted to all those who gave of their time, meeting with us and providing important insights into the existing system.

During the fall of 1994, some members of the committee participated in a daylong technical panel devoted to quality management issues. Members of the technical panel who met with committee members are listed in Appendix I.

Members of this panel assisted the committee by reviewing background materials and engaging in an important discussion regarding quality management issues. Appendix H lists the organizations that prepared written testimony for the committee's public meeting in the fall of 1994 and contains summaries of responses staff received to questions posed prior to the meeting. The committee also commissioned a number of papers to assist in preparation of this report. These papers are listed in Appendix J.

Regarding the writing of the report, the committee wishes to acknowledge particular contributions of the following individuals. The study director, Kate-Louise D. Gottfried, had overall responsibility for preparation of the report. With the invaluable assistance of Gary Penn, she edited the entire document. She also prepared the summary and the first drafts of Chapter 1, which were reviewed extensively by the entire committee. Chapter 2 was the collaborative effort of committee members and was synthesized by Mark Edwards in a commissioned paper. Chapter 3 is a compilation of work created from a commissioned paper by Daniel Strom, committee members, and staff.

Chapter 4 was also a joint enterprise. The first draft of the section on risk of exposure to low levels of ionizing radiation was written by Ronald Kathren and revised by committee members. The section on misadministrations benefited from a commissioned paper by Naomi Alazraki and committee members. The final section of this chapter drew on a paper commissioned from Paul Slovic. Chapters 5 and 6 are products of the entire committee's conceptual process, drafted by staff and revised repeatedly based on committee input. Appendix G was written primarily by Gary Penn, with some background material prepared by Eric Caplan and assistance of IOM senior staff, and committee members.

In addition, several members of the IOM's professional staff made important contributions to this report. Kathleen N. Lohr, as Director of the Division of Health Care Services, drafted the original proposal that led to this study and provided valuable guidance and editorial assistance over the duration of the project, including review and comment on several chapters. Richard A. Rettig lent his vast regulatory and study expertise in the formative stages of the report outline. Marilyn J. Field, Deputy Director of the Division of Health Care Services, also provided insights into the study process and review of Chapter 1.

A number of other IOM staff worked on this study. A. Everette James, Jr., assisted in creating the committee and establishing liaison with key individuals knowledgeable about the issues. Eric Caplan, research associate, was involved in the process initially and drafted a background paper on the quality management rule. Gary Penn joined the study seven months prior to review and rapidly assimilated vast quantities of complex material. Gary was a tremendous asset to the study during a critical juncture; his contributions to the writing and editing of the report are noteworthy. His quiet concentration and ever present calm and good humor moved the process forward.

Tania DeGolyer helped get the study under way. Jeanette Howard, who succeeded her, was a diligent and efficient assistant. Julie Fanburg stepped into a

process solidly under way and provided excellent assistance. Natassja Olsen arrived after the last meeting, stepping efficiently into the last critical stages of report preparation. We are all grateful for her competence. Richard Julian combined his mastery of software and attention to detail converting the report into camera-ready copy. Don Tiller provided excellent emergency assistance, Nina Spruill guarded our finances, and Claudia Carl managed the essential report review process. Rick Manning, study director of an earlier report, shared information with us as did John Zimbrick of the Commission on Life Sciences. Finally, this report benefited immeasurably from the meticulous efforts of Andrea Posner, who not only copy-edited it but also provided valuable organizational structure and coherence to the report as a whole.

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Summary

In November 1992, a misadministration[1] of radiation to a patient win Indiana, Pennsylvania, preceded a week-long series in the December 1992 Cleveland *Plain Dealer* entitled "Lethal Doses: Radiation That Kills." In response, Senator John H. Glenn (then chairman of the Governmental Affairs Committee) announced a congressional investigation into radiation medicine. This sequence of events prompted the U.S. Nuclear Regulatory Commission (NRC) to carry out an internal review of its Medical Use Program (described below) and to request an external review by the National Academy of Sciences' Institute of Medicine (IOM).

The NRC, pursuant to the Atomic Energy Act of 1954 (AEA), as amended,[2] is responsible for the regulation of nuclear reactors and reactor-generated byproduct material. Byproduct material consists of radionuclides produced during the process of nuclear reactor operation and accounts for approximately 10 percent of ionizing radiation used for medical purposes. Although much of this material is considered waste and must be properly disposed of, quantities of certain byproduct radionuclides are marketed for use by various industries, including the

[1] A misadministration is defined by the Nuclear Regulatory Commission, generally, as the administration of some radioactive substance in an amount that exceeds by a certain percentage the prescribed dosage. The percentage calculation depends upon the substance in question. A misadministration may also be the administration of a correct dosage, but of the wrong substance, or to the wrong patient. (For the full definition of misadministration, see 10 CFR 35.2 in Appendix D of the full report.)

[2] The acronym "AEA" as it appears throughout the report refers to the 1954 act, as amended, unless otherwise noted.

health care industry. (Throughout, the report such reactor-generated material will typically be referred to as "byproduct material" or "byproducts.") The radiation source involved in the Indiana, Pennsylvania, case was such a byproduct. As part of its broad monitoring responsibility, the NRC instituted its Medical Use Program to regulate the use of byproduct material in medicine. The review of this program is the subject of the NRC's charge to the IOM.

Reactor-generated byproduct material is a source of ionizing radiation, and as such, it poses risks to health and safety that sources of nonionizing radiation do not. Reactor-generated byproduct material is not the only source of ionizing radiation; other sources are radioactive materials that occur naturally or are accelerator-produced, and radiation produced by x-ray machines and particle accelerators.[3]

In examining the existing NRC Medical Use Program, the IOM Committee for Review and Evaluation of the Medical Use Program of the Nuclear Regulatory Commission compared the regulation of byproducts with the regulation of other sources of medically used ionizing radiation and with the regulation of medicine in general. The scope of this comparison was occasioned by an awareness of problems among the NRC, Congress, the states, and the regulated community that suggested the entire regulatory system needed to be examined. In particular, a major question for the IOM committee was whether the quantitative *risks* associated with reactor-generated byproduct material used in radiation medicine justify the extent to which byproducts are regulated compared to other sources of radiation in medicine and to medicine in general.

To provide the reader with background information, the successes and problems of radiation medicine and the clinical applications of ionizing radiation are discussed in the full report. The discussion of the current regulatory system pertaining to radiation medicine and the evolution of that system, together with an examination of several aspects of the risks that are associated with ionizing radiation in medicine, are the centerpiece of the report. The committee also considers in some detail general observations about the goals of regulation; the roles of the NRC, other federal entities, and the states; and the fee and non-fee costs of regulation (to the regulated community). The report describes a spectrum of seven alternative regulatory systems that were devised and debated by the committee, and presents the committee's findings, conclusions, and recommendations. The main focus of the report is on the existing regulatory framework for ionizing radiation in medicine and the committee's evaluation as to what would be an appropriate regulatory model for this particular aspect of medicine.

[3] Naturally occurring and accelerator-produced radioactive materials are collectively referred to as "NARM" to distinguish them from reactor-generated byproducts. The term "radionuclide" refers to both accelerator-produced materials and reactor-generated byproducts.

BENEFITS OF IONIZING RADIATION

Diagnostic and therapeutic clinical applications of ionizing radiation range from simple procedures like taking a chest x-ray to the complex regimens used to treat a brain tumor. Each of these applications benefits patients.

The diagnostic uses of ionizing radiation are classified under two basic headings: radiology and nuclear medicine. In radiology, the radiation administered is external to the patient; in nuclear medicine, it is internal. Ionizing radiation applied for therapeutic purposes is also typically classified into categories based on whether the source of the radiation is external or internal to the patient. These areas are called radiation oncology and teletherapy (external sources), brachytherapy (internal), and therapeutic nuclear medicine (internal).

The committee recognizes both the tremendous benefits derived from the use of ionizing radiation in medicine and its potential for harm. The committee's goal is to promote the benefits while advocating a regulatory structure that adequately protects the health and safety of patients, health care workers, and the public. An important component to this balance is patient access to radiation medicine. Fewer people will benefit if regulation makes radiation medicine needlessly expensive or less accessible to patients. Regulatory steps that lower the probability of risk only slightly, if at all, but seriously affect access to services through significant increases in cost or in the distance from patient populations should be foregone. The committee has identified and proposes to eliminate regulations that result in added costs but achieve little, if any, reduction in risk or added benefit for a patient's outcome and well-being or that of health care personnel.

THE REGULATORY FRAMEWORK

Regulatory authority over ionizing radiation in medicine is widely dispersed among several government agencies at the federal, state, and local levels. Among the federal agencies with oversight, the NRC has regulatory authority over the use of byproduct materials in medicine. The Food and Drug Administration (FDA) in the Department of Health and Human Services (DHHS) oversees the approval of radiation-producing devices and radiopharmaceuticals. In addition to the NRC, the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration, and the Department of Energy oversee exposure standards for the public and for workers. The transportation of radionuclides is regulated by another federal agency, the Department of Transportation (DOT). In some cases, regulatory standards, though crafted at the federal level, are administered by the states, as with the NRC's Agreement State Program (described below).

The Current Situation

The NRC currently regulates only 10 percent of all ionizing radiation used in medicine. The committee concluded, however, after assessing the existing regulatory system, that the health and safety of the public would be better served by uniform regulation of all such use. Therefore, the committee believes that the NRC's current system for regulating the use of byproduct material in medicine and for enforcing those regulations should be revised.

The committee further scrutinized the existing regulatory system and identified several problems that it concluded needed to be addressed. In particular, the committee found that the NRC's present set of regulations and its approach to enforcement are burdensome, costly, and unduly prescriptive. In addition, actions taken by the NRC against user institutions tend to be disproportionate to the violations, not so much in the magnitude of fines as in its public announcements of citations and its unrealistic paperwork demands.

The committee also determined that the benefits resulting from the NRC's efforts to reduce adverse events involving byproduct material, may not be commensurate with the constraints imposed. That is, the NRC's regulatory policy, although seemingly effective, may have gone beyond the point at which an additional dollar spent on regulation achieves an equivalent dollar of benefit to patients or the public. The implication is that decreasing somewhat the resources directed at regulation may not pose additional risks and, similarly, may yield benefits in the form of freeing resources that can be put to better or more efficient use.

The committee also found that the NRC intrudes into the practice of medicine (promulgation of the Quality Management Program and Notification, Reports and Records of Misadministrations, 10 CFR 35.32 and 35.33, respectively, involves the practice of medicine), and that there is little, if any, justification for the intensity of federal regulation of the use of byproducts in medicine given that the rest of ionizing radiation used in medicine and, indeed, most of the rest of medical practice, remains free from this level of federal oversight.

Finally, at the crux of this report lies a fundamental philosophical and political perspective concerning state and federal regulation. All ionizing radiation, with the exception of byproduct material, is currently regulated at the state level. Several federal agencies do still have regulatory authority over various aspects of the production, use, and disposal of ionizing radiation (see below). The committee, of course, cannot know whether states will continue their regulatory programs. It judged, however, given the strength and leadership of the Conference of Radiation Control Program Directors (CRCPD) and the *Suggested State Regulations for the Control of Radiation* (*SSRCR*) that the CRCPD promulgates, that state radiation programs would remain intact and expand to cover the area of byproduct use if federal regulation in this area were to be relaxed. In this way, all sources of ionizing radiation would be treated more uniformly than before, in

that they would *all* be subject to state regulation. Admittedly, the extent of state regulatory programs varies, but for the majority, the common denominator nationwide is the *SSRCR*.

If the NRC's Medical Use Program were to be eliminated, the basic structure of federal regulation and responsibility would remain in place under the regulatory alternatives considered by the committee. Federal agencies would retain responsibility for the generation, transport, nonmedical use, and disposal of radionuclides and for the approval of radiopharmaceuticals and certification or approval of equipment that generates ionizing radiation. In particular, this means that:

- the NRC and its Agreement States would continue to license the production of byproduct material for radiation-producing devices and radiopharmaceuticals in the medical context;
- the NRC and its Agreement States would, as relates to the nonmedical use of byproduct material (i.e., industrial, educational, and nonmedical research), continue to license the production and use of byproduct material;
- the DOT would continue to regulate the transport of radioactive materials;
- the EPA would continue to develop guidelines that set occupational and public exposure limits to be implemented by the respective federal agencies;
- the FDA would continue to regulate the manufacture and labeling of radiopharmaceuticals and medical devices;
- the FDA would continue to regulate the mammography program under the Mammography Quality Standards Act;
- the Department of Defense (DOD), the Department of Veterans Affairs (VA), and the Public Health Service (PHS) would continue to be responsible, under the regulations of the appropriate agencies, for the safe use of radioactive materials and radiation-producing machines in their hospitals and laboratories; and
- the Health Care Financing Administration for Medicare and Medicaid (and other federal agencies for other health care purchased from the private sector) would continue to develop reimbursement guidelines.

Additionally, where each state has a role in regulating the use of ionizing radiation in medicine, the committee assumes that the CRCPD would continue to develop suggested state regulations, to help coordinate state programs, and to act in the area of the nonmedical use of radioactive materials.

The NRC Medical Use Program

The NRC is responsible for regulating the "medical use" of byproduct materials. This responsibility, which the NRC carries out through its Medical Use

Program, derives from the NRC's general responsibilities for protecting public health and safety in connection with nuclear reactors. All other sources and medical uses of ionizing radiation are regulated by other entities, such as the states or the FDA.[4]

Through the Medical Use Program, the NRC licenses facilities, authorizes physician users, develops radiation safety regulations, sets criteria for determining misadministration of byproduct materials in medical use, orders prompt reporting of misadministrations, conducts compliance inspections, applies a system of sanctions for infractions of its regulations, and assesses and collects fees and fines. The program is administered through two different systems. In 29 states ("Agreement States"), the NRC formally delegates authority to regulate byproduct material to the state government. In the remaining 21 states ("Non-Agreement States"), the NRC directly licenses, monitors, inspects, and enforces its regulations for approximately 2,000 licensed users and institutions.

Over the years, the NRC has intensified its regulation of radiation medicine. In 1967, its predecessor, the Atomic Energy Commission (AEC), codified its medical regulations into a new Part 35 of Title 10 of the Code of Federal Regulations (CFR); this covered both the medical use of radioactive drugs and the use of radiation devices. although medical licensees are required to comply with many other sections of Title 10, Part 35 (Medical Use of Byproduct Material) is the most important.

Part 35 contains provisions designed to protect workers from radiation devices, beams, and sources. For example, to protect patients scheduled for radiation procedures, Part 35 requires quality management (QM) procedures (35.32), a measurement of each dose prior to administration (35.53), a survey of the patient after removal of temporary implants (35.406), and safety checks of teletherapy machines and rooms (35.615). Finally, other sections pertain to protection of the public and of patients not scheduled for radiation procedures; these provisions include surveys before returning radiation areas to unrestricted use (35.315, 35.415), criteria for releasing patients who have received doses of radioactivity (35.75), and QM redundancy procedures for verifying patient identity (35.32).

The NRC oversees medical use licensees through its inspection, investigation, and enforcement programs. Inspections involve (a) unannounced visits by NRC personnel to each licensed facility on a periodic basis (ranging from once a year to once every four years, depending on the scope of the license), and (b) special inspections to follow up a particular incident. Inspections are intended to ensure that licensed programs are conducted in accordance with NRC requirements, with specific provisions of the license, and with the health and safety requirements

[4] Boron neutron capture therapy, which does not involve byproduct material but rather uses radiation directly from a nuclear reactor to treat patients, is also regulated by the NRC.

of workers and the general public. NRC inspectors utilize direct observations of work activities, interviews with workers, and detailed reviews of licensee records to determine compliance with regulatory requirements.

Enforcement actions may be taken against licensees when violations of NRC regulations are discovered. Such violations range from failure to follow procedures detailed in a QM program to threats to public health and safety. Sanctions include more frequent inspections, release of negative publicity to the media, civil fines and penalties, and license revocation.

The discussion throughout the report focuses on "quality management" as the concept has been defined by the NRC and put into operational form through its QM rule. The committee recognized, however, that issues relating to the measurement and improvement of quality of health care go far beyond this narrow interpretation. Given the complexities of its charge, the committee opted not to examine issues relating to quality assurance in any detail, but it recognized that the NRC's approach was not consistent with contemporary efforts by health care institutions and plans to implement continuous quality improvement programs within their own facilities and by their own practitioners and members.

The Quality Management Rule

The NRC's QM rule calls upon NRC licensees to establish a QM program in compliance with 10 CFR 35.32 and 35.33 in three circumstances: (1) if they administer radiation from sealed sources containing byproduct material for therapy (brachytherapy); (2) if they administer cobalt teletherapy; or (3) if they administer therapeutic unsealed radionuclides (therapeutic nuclear medicine). The rule also applies to any diagnostic administration of greater than 30 microcuries of sodium iodide containing I-125 or I-131. Moreover, it requires NRC licensees to submit written certification that they have implemented a QM program, Whereas NRC licensees have been living with this rule since January 1992, Agreement States were not required to follow suit until January 1995.

The QM rule is a performance-based approach to quality management. This approach has five specific objectives:

1. Prior to an administration, a written directive must be prepared.
2. Prior to each administration, the patient's identity must be verified using more than one method as the individual named on the written directive.
3. Final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery must be in accordance with the respective written directives.
4. Each administration must be in accordance with the written directive.
5. Any unintended deviation from the written directive must be identified and evaluated, and appropriate action must be taken.

The NRC Agreement State Program

The NRC Agreement State Program provides an opportunity for the NRC to "discontinue" its regulatory authority over byproducts; it allows states to assume responsibility to license and regulate byproduct material, source material, and small quantities of special nuclear material. The NRC's authority regarding radiological health and safety aspects of nuclear materials is transferred to the states through a formal agreement between the governor of the state and the NRC.[5] Currently, there are 29 Agreement States, and 4 other states are exploring agreement status.

An Agreement State arrangement requires that the NRC conclude that a state's radiation control program "is compatible with the Commission's, meets the applicable parts of Section 274 [of the AEA] and … is adequate to protect the public health and safety." Once the state has passed enabling legislation to establish its authority to enter into the agreement, and after its radiation control program is found to be both adequate and compatible with NRC requirements, state assumption of authority becomes effective on the date the agreement is signed.

Section 274j of the AEA stipulates, however, that the NRC may terminate or suspend all or part of an agreement with a state if it deems that such action is necessary to protect public health and safety. Although Agreement States administer their own programs and regulate licensees, the NRC maintains significant authority over the states. Biennially, the NRC's Management Review Board reviews each state's performance to determine whether its program is "adequate" and to ensure that its regulatory requirements do not significantly deviate from the NRC's.

Despite these reviews, NRC oversight of the Agreement State Program has been criticized for lacking data adequate for comparing the regulatory performance of the NRC (for the 21 states it regulates) with that of Agreement States. In April 1993, the General Accounting Office (GAO) reported that the NRC lacks common performance indicators for inspection backlogs, radiation overexposures, and numbers of violations. Because the programs of NRC-regulated states and Agreement States use different indicators to measure effectiveness, the GAO report asserts that the NRC cannot determine whether people in each state are receiving the same minimum level of protection.

Partly in response to such criticism, the NRC amended and clarified its policies for overseeing the Agreement State Program. As of 1995, Agreement States are required to report data on misadministrations in the same form and using the same definitions as those used by the NRC for the Non-Agreement States. In May 1995, a new "Final Statement of Principles and Policy for the

[5] Public Law 83-703 (68 Stat. 919) (1954) as amended by Public Law 86-373 (73 Stat. 688) (1959), sec. 1, added sec. 274, Cooperation with States, which includes the criteria for these agreements.

Agreement State Program" established a stronger performance evaluation process; it was intended to enable the NRC to take more effective, graduated actions to ensure that the radiation control safety programs of the Agreement States remain adequate and compatible.

ALTERNATIVE REGULATORY SYSTEMS

Having examined the available information and data pertaining to the existing regulatory system and its inherent strengths and weaknesses, the committee proceeded to explore potential regulatory options. Specifically, it examined a wide spectrum of alternative structures through which all ionizing radiation in medicine might be regulated. By elucidating the pros and cons of each alternative, the committee sought to identify problems within the current system and to determine which alternative would be most likely to deliver the greatest net benefit to society. Chapter 5 of the report provides an overall assessment of each alternative and explains the rationale behind the alternative that the committee ultimately preferred.

In considering the proposed alternatives briefly described below, the reader should remember one key point: in all but one model (the "laissez-faire" approach), the basic structure of federal regulation and responsibility would remain in place, except for those alternatives that propose to eliminate the NRC's Medical Use Program. In particular, federal agencies would retain responsibility for the generation, transport, nonmedical use, and disposal of radionuclides and for the approval of radiopharmaceuticals and certification or approval of equipment that generates ionizing radiation.

Seven Alternative Structures

The alternatives considered pertain to two relevant parts of the CFR: 10 CFR Part 35: Medical Use of Byproduct Material, and Part 20: Standards for Protection Against Radiation. The focus is on those CFR provisions as they affect institutions and individuals involved in the medical and biomedical research use of radiation in medicine. The alternatives reflect the thinking of the committee and incorporate certain assumptions that cannot be substantiated in any quantitative way.

Nevertheless, the committee believes that these alternatives illustrate the theoretical spectrum, ranging from essentially no regulation—Alternative B, a market-based approach—to the other extreme, creation of an all-encompassing regulatory apparatus pertaining to all of health care—Alternative G. Two versions of Alternative A, essentially the status quo, retain the existing regulatory system. alternatives C, D, E, and F present a more conventional continuum for addressing regulation. These four alternatives examine the differences between exclusive state regulation (C), state regulation accompanied by a federal advisory

presence (D), state regulation accompanied by limited federal authority (E), and centralization of federal regulation at the federal level (F). In particular, the NRC retains responsibility for licensing the production of byproduct material for use in radiation-producing devices and radiopharmaceuticals. Chapter 5 of the report describes each alternative and discusses its strengths and limitations. The chapter also provides an overall assessment of the alternatives and identifies the one preferred by the majority of the committee.

Assessment of the Alternatives

The discussion of the committee's seven alternative regulatory systems examines the extremes and then moves toward the preferred alternative.

The committee rejected retaining the status quo described in the two versions of Alternative A, essentially because they do not address the committee's judgment that all ionizing radiation in medicine ought to be administered and regulated more uniformly, rather than having byproduct use under federal (NRC) regulation and the other 90 percent of medical use of ionizing radiation regulated under other mechanisms. Alternative A also does not address the committee's desire to shift federal involvement from the NRC to the DHHS.

The committee also rejected the laissez-faire approach in Alternative B. Although laissez-faire markets work well for many goods and services, the market for health care is distinctive for several reasons. These include the fact that health insurance insulates people from the true price of medical services.

Many committee members had little expectation that the marketplace, the malpractice system, and the watchful eyes of professional societies, by themselves, could weed out incompetent practitioners and ineffective procedures. Because Alternative B precludes a governmental role in maintaining standards, the committee was concerned that the quality of the delivery of ionizing radiation in medicine would sink to a lowest common denominator, a level considered too risky even by those who believe that the existing regulatory system is incommensurate with the actual risks associated with ionizing radiation. Finally, the committee recognized that this laissez-faire approach would be unacceptable to most Americans.

Moving to the other extreme of the scale, the committee rejected the Health Finance Agency (HFA) posed in Alternative G. This alternative, rather than letting providers and patients make choices essentially without government interference, could limit choices. As posed by the committee, the HFA would set guidelines for appropriate health care interventions and then enforce compliance with those guidelines through nonpayment, exclusion from federal programs, or similar regulatory steps. The crucial problem for the committee is that such guidelines and regulatory actions would, as this alternative was envisioned, necessarily extend beyond the use of ionizing radiation to cover all aspects of health care. The committee, asked to address a very specific problem regarding regulation

of ionizing radiation in medicine, was unwilling to recommend this all-encompassing solution. Promoting such a system might or might not result in much needed controls of escalating health care costs or expand access to care, but neither Congress nor the country as a whole, in the view of the committee, is prepared for such a massive reorganization of the health care system.

Alternative F, which centralizes regulation of ionizing radiation in one federal agency, has several appealing characteristics. It would achieve regulatory clarity and simplicity by transferring the authority to regulate ionizing radiation used in medicine to an agency responsible for federal oversight of health care. However, as the committee explored this alternative, it could find little reason for creating an expanded federal role in the regulation of accelerator-produced radionuclides and machine-produced radiation—that is, the 90 percent of radiation medicine now regulated at the state level. Although some committee members thought that safety should be increased and usage reduced for some radiation sources, such as x-ray machines, they did not see pursuing these goals as the job of the federal government. A federal agency might fund research, foster professional consensus, or advocate improved health care, but in the committee's view a federal regulatory agency responsible for all uses of ionizing radiation in medicine would be expensive and unwieldy. Furthermore, the benefit from such an expanded program would be questionable and would alter the practice of radiation medicine. Although not a reason in and of itself to preclude such an expansion, such a change may require time-consuming enabling legislation. From a cost-benefit perspective, the committee saw little reason to pursue this alternative.

The committee found many appealing qualities in Alternative C, in which all regulatory authority is given to the states. Although several federal agencies regulate radiopharmaceuticals, radiation-emitting medical devices, transport of radionuclides, and radiation exposure of workers and the public, most states regulate the use of all ionizing radiation in medicine except for byproduct materials. State government is, therefore, a logical locus for more comprehensive and consistent regulation of these health care interventions.

Although this system of state regulation is not perfect, it seems to function to the satisfaction of the public, its representatives, and health care practitioners. Furthermore, the committee sees little difference between radionuclides generated naturally or by accelerator or reactor, and it could find no real evidence to suggest that state regulation of the first two sources is not working well. Thus, it concluded that primary state regulation would be appropriate.

One concern with Alternative C, however, was that states could decide not to regulate in this area of ionizing radiation at all, effectively instituting Alternative B within their borders. In the end, the committee was not comfortable with this possibility. It wanted to be sure that state regulation of ionizing radiation would evolve in accordance with scientific and technological advances; that Non-Agreement States would be assisted with any transition from NRC regulation;

and that information sharing and monitoring of the general public health and safety would be enhanced. Thus, the committee narrowed its focus to Alternatives D, federal guidance, and E, limited federal authority. It examined the notions of federal guidance and federal authority very closely and spent a great deal of time debating the virtues and drawbacks of these remaining strategies.

Alternative E provides for the exercise of reserve federal authority if a state chooses not to expand its radiation control program to include byproducts. This is the primary difference between Alternatives D and E. The committee's concern about this alternative focused on the delegation of federal regulatory authority for what is likely to be a minority of states. Federal regulation of medical uses of ionizing radiation in states without a program for byproducts also raises the question of what the minimum level of regulation ought to be and how minimum standards might be established. In effect, Alternative E would replicate the existing NRC Agreement State Program. Thus, the committee arrived at its preferred choice: Alternative D.

The Preferred Choice: Alternative D, Federal Guidance

Alternative D modifies state regulation (Alternative C) by adding a federal agency with two key roles. First, the agency would be responsible for working in conjunction with the CRCPD and other professional organizations to provide voluntary guidelines and model regulations for states. Second, it would assume a leadership role for the regulated community.

Although, under Alternative D, states cannot be compelled to accept the voluntary guidelines or the *SSRCR*, a variety of forces can greatly influence them to do so. For example, the committee envisions a collaborative effort of the proposed federal agency, the states, the CRCPD, and other professional organizations not unlike the process utilized in developing the mammography regulations that involved the FDA, the American College of Radiology, and other professional organizations. This would facilitate an interactive process and allow an exchange of ideas, so that controversies might be resolved before implementation. Respect for and investment in the process would foster a keen vested interest in successful implementation on the part of all participants.

Other reasons exist for states to adopt voluntary guidelines and the *SSRCR*. Professional peer pressure, from the people within each state who are involved in developing the *SSRCR*, would exert substantial influence to make the process work. Consumer groups and the media, seeking to ensure that the citizenry is protected, would also exert pressure. State medical societies would also want regulatory oversight to prevent unskilled users of radiation from embarrassing the medical profession by their questionable practices.

Finally, corporate pressure from manufacturers in a state that does not have a program cannot be underestimated. Alternative D would mean that, for facilities in any state to use byproduct materials, that state would have to establish a

regulatory program that includes reactor-generated byproduct material. The NRC and its Agreement States would continue to regulate the *manufacture* of byproduct material for use in radiation devices and radiopharmaceuticals; thus, manufacturers would not be able to distribute radioactive byproduct material to users unless they were licensed by their states. Consequently, this requirement provides an inducement to states to expand or revise their existing radiation control programs to include byproducts.

The committee was also concerned that a purely voluntary agency such as the CRCPD, sustained by states, professional associations, or both, might receive insufficient funding during periods when states had fiscal crises. A modest federal presence could head off potential difficulties at what the committee believed would be a relatively low cost.

The committee determined that this agency should be one other than the NRC, because the NRC's mission is to regulate only those materials used in medicine that are products of nuclear reactors. The NRC, therefore, has responsibility for only 10 percent of ionizing radiation in medicine. The more logical choice for a responsible agency would be the DHHS, which has an extensive history in regulating radiation.

Eliminating federal regulation of byproducts made some committee members apprehensive about the possibility of decrements in quality of care. This point was discussed at great length during the study. The committee's conclusion was that Alternative D would be sufficient to protect quality of care and public health, and rested its conclusion on two considerations.

The first consideration was that current federal regulation of pharmaceuticals, medical devices, equipment, transport, disposal, and worker and public exposure would continue under Alternative D. In addition, the federal government would have to regulate the use of ionizing radiation in medicine in PHS, VA, and DOD medical facilities. Moreover, nothing in this alternative would weaken current licensure or certification requirements for physicians and other health workers. Radionuclides per se would continue to be regulated stringently to ensure that they do not injure the public.

Additionally, the NRC would retain responsibility for licensing manufacturers that produce byproduct material for use in radiation devices and radiopharmaceuticals. These manufacturers must adhere to NRC regulations for their licensure and thus could not sell byproducts to unlicensed users. Consequently, as noted above, this requirement provides an inducement to states to expand their existing radiation control programs to include byproducts.

The second consideration is that millions of people have been treated with machine-produced radiation and accelerator-produced radionuclides with no indication of injury to them or to the public at large beyond that common to medical procedures in general. Current state regulations seem to work for non-byproduct ionizing radiation in medicine, and the committee expects that byproduct materials can be accommodated in the state systems. The burden is on

the states to adequately protect the public health and safety of their citizens by devising effective regulatory programs that encompass byproducts. Because the states already provide effective regulation for non-byproduct radiation in medicine, the committee sees no good argument for subjecting all of radiation medicine to federal regulation for the first time.

Nonetheless, the presence of a federal agency, the purpose of which is leadership and guidance rather than regulation, could add a great deal to the effectiveness of a state-based regulatory system. The federal agency as envisioned in Alternative D would fulfill several functions: assisting states in establishing regulatory programs, training inspectors, addressing problematic incidents of national concern, educating the public as to the benefits and risks of radiation medicine, collecting risk data so that policy decisions might be made by the states, conducting research so that the science of radiation medicine continues to advance, and monitoring the effects of deregulation. By acting in these traditional capacities, the federal agency would contribute to an efficient, safe means of regulating ionizing radiation in medicine without imposing more requirements on one aspect of ionizing radiation than on another.

FINDINGS AND CONCLUSIONS

During its deliberations, the committee reviewed information from a variety of sources, including commissioned papers, literature reviews, site visits, official presentations by NRC personnel, a public hearing, and interviews with radiation safety officers. The lack of data for comparing byproduct material, naturally occurring and accelerator-produced radioactive material (NARM), and machine-produced radiation limited the scientific basis of the committee's findings.

The committee's findings are outlined in Chapter 6 of the report by category: risks and benefits; regulation; the regulated community; and private, voluntary involvement in radiation safety. In brief, the committee's major findings and conclusions include the following:

- The use of ionizing radiation in medicine offers tremendous benefits to patients but also carries a nontrivial potential for harm.
- Compared to the regulatory systems in place for the other 90 percent of medical use of ionizing radiation, the more detailed reporting and enforcement systems required for byproduct materials do not seem to result in even a marginal decrease in risk to providers, patients, or members of the public.
- Equal treatment of all ionizing radiation in medicine would be a sensible national policy insofar as the risks of reactor-generated byproduct material and other forms of radiation are equal.

The most important difference between radiation sources is that machines produce radiation only when they are activated, whereas radionuclides produce

radiation until they decay fully. In terms of their uses in health care, this difference, which requires special considerations in the storage, shipping, and handling of radionuclides, is minor when compared to the similarities of the medical applications of the various types of radiation.

- The regulatory system specifically covering the medical use of reactor-generated byproduct material has outlived its original logic.

Nuclear medicine and radiation oncology expanded greatly with the availability of reactor byproduct material for peaceful uses; it is understandable that the Atomic Energy Commission, and later the NRC, were at the outset delegated general authority for regulation in these fields. Today, however, many accelerator-produced radionuclides play a central role in the practice of nuclear medicine, and in radiation oncology, accelerator-produced radiation continues to displace the use of byproduct radiocobalt. Consequently, the unequal treatment of different sources of ionizing radiation in medicine can be construed as illogical if not counterproductive.

- Taking the view that regulation of ionizing radiation in medicine should be considered in its entirety, the committee concluded that special treatment of reactor-generated byproduct material is inappropriate. It also concluded that the regulation that would be appropriate should not be conducted by the NRC, given that the risks are spread more or less evenly across all sources of ionizing radiation.

The committee has identified and proposes to eliminate regulations that achieve little reduction in risk but result in excessive costs.

All these factors, taken together, argue for the need to remove regulatory authority over the use of byproduct material in medicine from the NRC and to replace it with a broader and more appropriate system for the regulation of ionizing radiation in medicine. To bring this about, the committee developed eight interlocking recommendations, as discussed next.

RECOMMENDATIONS

The committee's specific recommendations were developed for three different audiences: (a) proposals for Congress, (b) steps for immediate action by the NRC, and (c) actions for professional entities.

A: Recommendations to Congress

A1. The committee recommends that Congress eliminate all aspects of the NRC's Medical Use Program, 10 CFR Part 35, and those regulatory

activities conducted under 10 CFR Part 20 that are applicable to medical uses.

The committee proposes that Congress revoke the NRC's authority to regulate the medical and biomedical research uses of reactor-generated byproduct material. By nullifying the NRC's authority, Congress can effectively relinquish to each state, at its option, responsibility for regulation of reactor-generated byproduct material. Elimination of the NRC's Medical Use Program should only take place once the second recommendation to Congress (A2, below) has been fulfilled. Additionally, any legislation that accomplishes the revocation of Part 35 should provide for a transition period, during which the federal government transfers authority to the states.

Rescission of authority at the federal level for regulation of the medical uses of byproduct material has three benefits. First, it eliminates prescriptive and costly regulations that yield marginal risk reduction. Second, it shifts responsibility, by giving state governments authority over the health and safety of their citizens. Third, it promotes uniform treatment, in that radionuclides and machine-produced radiation are regulated by a single level of government at equal intensity, regardless of their source.

It should be emphasized, however, that the NRC would retain regulatory authority over manufacturers of byproduct materials used in medicine, such as nuclear power plants and radiopharmaceutical companies. Also, as mentioned in Chapter 5, other federal agencies, such as the FDA, the DOT, and the EPA, would retain their regulatory authority over radiation.

A2. The committee recommends that Congress direct the Secretary of Health and Human Services to support, coordinate, and encourage the following activities involving regulation of all ionizing radiation in medicine:

- **a. supporting the operation of the Conference of Radiation Control Program Directors;**
- **b. providing a venue for the review and evaluation of *Suggested State Regulations for Control of Radiation;***
- **c. assisting states in implementation of their regulations;**
- **d. aiding in assessment of the effectiveness of state programs through the collection and analysis of data;**
- **e. helping develop survey methods by which the rate of adverse events for a wide range of procedures and devices might be measured;**
- **f. monitoring the effects of deregulation;**
- **g. enhancing training and standards for health care personnel; and**
- **h. investigating future significant radiation medicine incidents.**

The Secretary of the DHHS can accomplish the above functions either by creating a new office within the DHHS or by assigning these functions to an existing office, such as the FDA's Center for Devices and Radiological Health. The committee deliberately chooses not to suggest an exact location, as it believes that the Secretary is in a better position to make such a decision.

The committee recommends that the functions of this agency include the responsibility of funding the CRCPD and of encouraging and assisting the CRCPD in the continuous revisions of model legislation for adoption by the states. This "bully pulpit" role lends credibility to the CRCPD's efforts by giving it a federal imprimatur. Also, this nonregulatory federal entity, by convening the appropriate professional organizations to review and analyze new information that comes to light, provides a vehicle for integrating and coordinating efforts that will have national consequences.

B: Recommendations to the Nuclear Regulatory Commission

B1. The committee recommends that the NRC immediately relax enforcement of 10 CFR 35.32 and 35.33 through its present mechanisms.

Appreciative of the weight of the NRC's regulatory responsibilities, the committee nevertheless explored problems with the NRC's Medical Use Program that should be addressed. In hearings, committee members heard consistent criticisms of NRC regulations and enforcement as burdensome, costly, and overly prescriptive. The NRC's regulatory program for the industrial sector is based on the premise that radiation and people should be kept apart. In the medical context, radiation and people are intentionally brought together in an effort to improve health and save lives. Thus, the committee found that the regulated community's desire for a collegial, more cooperative approach on the part of the NRC could improve the quality of medical care and lower the rates of misadministrations.

The level at which the NRC currently enforces 10 CFR 35, sections 35.32 and 35.33—through detailed and voluminous documentation, reporting, and penalties—is inconsistent with the NRC's Medical Policy Statement, which favors minimum regulatory intrusion into the practice of medicine. Indeed, NRC's written regulations nowhere require such strict enforcement. The NRC has the authority to cease its present methods of enforcing sections 35.32 and 35.33, of its own volition. At a minimum, the NRC could immediately notify its licensees of its intent to relax its detailed enforcement and monitoring of sections 35.32 and 35.33, until a more permanent change is effected. This single change is a move toward bringing NRC regulations into line with the way that medical care in general and ionizing radiation in particular (except for byproduct materials) are regulated.

Reporting requirements currently in section 35.33 would not be entirely abandoned. On August 26, 1993, the NRC and the FDA created a memorandum of understanding to coordinate existing NRC and FDA regulatory programs for medical devices, drugs, and biological products that use byproduct, source, or special nuclear material. The committee urges the NRC to continue to cooperate with the FDA as provided in their memorandum of understanding to obtain data on devices, drugs, and biological products that relate to device malfunction, serious injury, and death. This coordinated effort between the two agencies will capture important data on technology and human (user) error related to device use but will exclude information relative to medical or technical judgment. This also reinforces the notion that the NRC, like the FDA, should not intervene in the practice of medicine.

B2. The committee recommends that the NRC initiate formal steps under the Administrative Procedure Act to revoke Part 35 in its entirety, if Congress fails to act within two years in response to the two recommendations to Congress stated above.

In addition to overly stringent enforcement, the regulations themselves are excessive and duplicative: 10 CFR Part 35 covers areas that either are already regulated at the institutional level or are best left to the states, to professional societies, and to patients in consultation with their doctors. States regulate the medical uses of other forms of ionizing radiation and, as discussed below, could easily fold byproduct material into their regulatory programs. The CRCPD could add byproduct material to its suggested state regulations. These additions could incorporate relevant concepts currently in Part 35 (see discussion below under Recommendation C1 to the CRCPD and states). The FDA collects data on adverse effects of radiopharmaceuticals and incidents of failure of radiation-emitting medical devices, and it could assume the monitoring responsibilities of the NRC.

Quality improvement programs are put in place by institutions and health plans, with the support of the Joint Commission on Accreditation of Healthcare Organizations and other private accreditation organizations. Doctors have ethical obligations, codified in professional standards, for informing patients of medical errors. The committee believes that the relatively low misadministration rate could be maintained by less stringent programs that are administered at the state level by professional societies, and by existing liability law.

The committee strongly endorses the formal route of notice and comment, subject to the Administrative Procedure Act, to accomplish the rescission of all of Part 35. The committee recognizes that this process will take some time.

B3. The committee recommends that the NRC separate the costs of formulating regulations from the costs of administering those regulations.

Fees cover both development and administration of regulations. Licensing fees charged to health care facilities to meet the cost of the existing NRC program are becoming increasingly expensive as more states become Agreement States. The reason is that the NRC program and overhead costs do not drop, but the costs are spread over institutions in fewer and fewer states.

Congress ordered the NRC to recover 100 percent of its costs from user fees, and thus all NRC costs have been divided among the institutions it licenses. Congress also permitted the NRC to discontinue its authority over states interested in entering into formal agreements with the NRC, becoming Agreement States subject to NRC oversight. These Agreement States do not bear any of the NRC's costs. As more states have decided to become Agreement States, the NRC's costs have declined somewhat, but not nearly in proportion to the number of institutions it licenses. The result is rapidly rising fees levied on the institutions it does license, and this in turn increases the pressure for the remaining states to become Agreement States. This existing system is unfair. Only NRC-licensed institutions should bear the NRC's costs of licensing and inspection, whereas the costs of developing standards should be borne by all institutions, whether or not they are located in NRC-regulated states.

C: Recommendations to the Conference of Radiation Control Program Directors and to the States

C1. The committee recommends that the Conference of Radiation Control Program Directors incorporate into its *Suggested State Regulations for Control of Radiation* any relevant concepts from 10 CFR Part 35 that are not already integrated in those suggested regulations.

The CRCPD, comprising the radiation control programs in the 50 states (except Wyoming), the District of Columbia, and Puerto Rico, has developed and improved model state legislation for the regulation of all of ionizing radiation in medicine. The model legislation was first crafted by the Council of State Governments in 1962 and is revised periodically, most recently in 1991. On an ongoing basis the CRCPD has reviewed and revised its suggested state regulations in accordance with evolving scientific and technical information. Although the committee has determined that provisions in 10 CFR Part 35 need not be regulated at the federal level, it does encourage the CRCPD to undertake a systematic review and analysis of the concepts in Part 35 for possible adoption where relevant and appropriate.

C2. The committee recommends that all state legislatures enact enabling legislation to incorporate the regulation of reactor-generated byproducts into existing state regulatory programs.

Currently, almost all states have legislation governing the regulation of radiation, as noted in Chapter 3. These statutes include, to varying degrees, naturally occurring and accelerator-produced radionuclides and machine-produced radiation. If Congress acts in accordance with the committee's recommendation to transfer authority for regulation of reactor-generated radionuclides to the states, the states should either amend their existing radiation legislation to encompass reactor-generated byproduct material or promulgate new legislation that addresses byproduct material. States that did not include byproduct material in their existing regulatory programs, which means they would not license users within their borders, would effectively preclude those users from obtaining byproduct material from manufacturers, which (by other NRC regulations) require proof of licensure before selling the material.

Although the committee cannot guarantee that states will effectively regulate byproduct material, it believes that they will. This conclusion is based on the fact that states have effectively regulated naturally occurring and accelerator-produced radioactive material in the past and continue to do so. The CRCPD's *SSRCR* have been adopted, to varying degrees, by the majority of states. Additionally, the current NRC Agreement States already regulate byproduct material within their borders. There is no reason to think that any of these programs will be disbanded. Additionally, the Joint Commission on Accreditation of Healthcare Organizations, the threat of malpractice suits, and the fear of adverse publicity in a competitive health care market all weigh against laxity that might lead to or not prevent adverse events.

C3. The committee recommends that the Conference of Radiation Control Program Directors and the states continually reevaluate their regulations and procedures pertaining to radiation medicine to ensure congruence with evolving scientific understanding of radiation bioeffects and to be in accord with advances in knowledge regarding benefits and risks related to medical and biomedical research uses of ionizing radiation in medicine.

As the CRCPD and the states fulfill their advisory, regulatory, and enforcement obligations, their revised recommendations, regulations, and procedures will reflect developments in scientific, technological, and regulatory knowledge. The committee wishes to stress the importance of promulgating and maintaining recommendations, regulations, and procedures in accord with state-of-the-art information. This is perhaps the most important function of the federal advisory agency envisioned in Alternative D described above—providing leadership and a level of assurance that the states are equipped with the most up-to-date information on the scientific and technical fronts.

CONCLUDING OBSERVATIONS

The most important goals of regulation of radiation medicine are to assure the safety of patients, workers, and the public and to ensure that the benefits of regulation will outweigh the risks. Whether the existing NRC regulatory system is the best approach for achieving this outcome was the focus of the committee's inquiry. Extensive discussion, throughout the study process, about the virtues and drawbacks of federal regulation, as opposed to state regulation, took place. Ultimately, from a wide spectrum of alternative approaches to the regulation of radiation medicine (including the existing one), the committee selected Alternative D, which removes regulatory authority from the NRC, shifts federal guidance to the DHHS, and delegates regulatory responsibility for byproduct material to the states, with the proviso that only licensed users would have access to byproduct material.

With the articulation of this alternative and the recommendations set forth above, the committee believes that it has fulfilled its assigned task. This report offers to the nation an approach to the regulation of all ionizing radiation in medicine that will adequately protect the public's health and safety and assure broadest access of the public to the benefits of the full range of medical uses of ionizing radiation.

SUMMARY OF RECOMMENDATIONS TO THE CONGRESS, THE NUCLEAR REGULATORY COMMISSION, THE CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, AND THE STATES

The committee recommends that:

A1. Congress eliminate all aspects of the NRC's Medical Use Program, 10 CFR Part 35, and those regulatory activities conducted under 10 CFR Part 20 that are applicable to medical uses.

A2. Congress direct the Secretary of Health and Human Services to support, coordinate, and encourage the following activities involving regulation of all ionizing radiation in medicine:

a. supporting the operation of the Conference of Radiation Control Program Directors;
b. providing a venue for the review and evaluation of *Suggested State Regulations for Control of Radiation;*
c. assisting states in implementation of their regulations;
d. aiding in assessment of the effectiveness of state programs through the collection and analysis of data;

e. helping develop survey methods by which the rate of adverse events for a wide range of procedures and devices might be measured;
f. monitoring the effects of deregulation;
g. enhancing training and standards for health care personnel; and
h. investigating future significant radiation medicine incidents.

B1. The NRC immediately relax enforcement of 10 CFR 35.32 and 35.33 through its present mechanisms.

B2. The NRC initiate formal steps under the Administrative Procedure Act to revoke Part 35 in its entirety, if Congress fails to act within two years in response to the two recommendations to Congress stated above.

B3. The NRC separate the costs of formulating regulations from the costs of administering those regulations.

C1. The Conference of Radiation Control Program Directors incorporate into its *Suggested State Regulations for Control of Radiation* any relevant concepts from 10 CFR Part 35 that are not already integrated in those suggested regulations.

C2. All state legislatures enact enabling legislation to incorporate the regulation of reactor-generated byproducts into existing state regulatory programs.

C3. The Conference of Radiation Control Program Directors and the states continually reevaluate their regulations and procedures pertaining to radiation medicine to ensure congruence with evolving scientific understanding of radiation bioeffects and to be in accord with advances in knowledge regarding benefits and risks related to medical and biomedical research uses of ionizing radiation in medicine.

1

Introduction

In November 1992, a misadministration[1] of radiation to a patient in Indiana, Pennsylvania, preceded a week-long series in the December 1992 Cleveland *Plain Dealer* entitled "Lethal Doses: Radiation That Kills." In response, Senator John C. Glenn (then chairman of the Governmental Affairs Committee) announced a congressional investigation into radiation medicine. This sequence of events influenced the U.S. Nuclear Regulatory Commission (NRC) in seeking both an internal review of its Medical Use Program and an external review from the National Academy of Sciences' Institute of Medicine (IOM).

The NRC, pursuant to the Atomic Energy Act of 1954 (AEA), as amended,[2] is responsible for the regulation of nuclear reactors and reactor-generated byproduct material.[3] As part of this broad responsibility, the NRC instituted its

[1] A misadministration is defined by the Nuclear Regulatory Commission, generally, as the administration of some radioactive substance in an amount that exceeds by a certain percentage the prescribed dosage. The percentage calculation depends upon the substance in question. A misadministration may also be the administration of a correct dosage, but of the wrong substance, or to the wrong patient. (For the full definition of misadministration, see 10 CFR 35.2 in Appendix D.)

[2] The "AEA" abbreviation, as it appears throughout the report, refers to the 1954 act, as amended, unless otherwise noted.

[3] The NRC regulates "reactor-generated byproduct material." Byproduct material consists of radionuclides produced during the process of nuclear reactor generation. Although much of this material is considered waste and must be properly disposed of, quantities of certain byproduct radionuclides are marketed for use to various industries, including the health care industry. Throughout this report such reactor-generated material will typically be referred to as "byproduct material" or "byproducts." The radiation source involved in the Indiana, Pennsylvania, case was a reactor-generated byproduct.

Medical Use Program to regulate the use of byproduct material in medicine. The review of this program is the subject of the NRC's charge to the IOM.

Byproduct materials include such radionuclides as cobalt-60, iodine-131, iodine-125, and iridium-192, all of which are used for diagnosis and treatment of cancer. They are sources of ionizing radiation and, as such, pose risks to health and safety that sources of nonionizing radiation do not.[4] Radiation is ionizing when it dislocates electrons from atoms to produce positive ions and free electrons. (Nonionizing radiation pertains to other types of electromagnetic radiation at wavelengths that do not cause ionization, such as those used in magnetic resonance imaging, microwaves, and radar). Byproduct material is not the only source of ionizing radiation; other sources are radioactive materials that occur naturally or are accelerator produced, and radiation (not materials) produced by x-ray machines and particle accelerators.[5]

In examining the existing NRC Medical Use Program, the IOM Committee for Review and Evaluation of the Medical Use Program of the Nuclear Regulatory Commission compared the program not only with the regulation of sources of medically used ionizing radiation other than reactor-generated byproduct material but also with the regulation of medicine in general. The scope of this comparison was occasioned by an awareness of problems among the NRC, Congress, the states, and the regulated community that the entire regulatory system needed to be examined. In particular, a major question for the IOM committee was whether the scientific data on risks associated with reactor-generated byproduct material used in radiation medicine justify the extent to which it is regulated compared to other sources of radiation in medicine and to medicine in general.

ERRORS AND SUCCESSES, BENEFITS AND PROBLEMS OF RADIATION MEDICINE

The Indiana, Pennsylvania, incident—one of the precipitating factors in the NRC's decision to seek an independent review of its Medical Use Program—involved Sara Mildred Colgan, an 82-year-old woman who had worked most of her life as a physical therapist at a home for disabled children before retiring in the mid-1970s. In October 1991, she was diagnosed with cancer.

[4] This is not to imply that there is no controversy or doubt concerning the possible effects of nonionizing radiation.

[5] Naturally occurring and accelerator-produced radioactive materials are collectively referred to as "NARM" to distinguish them from reactor-generated byproduct materials. The term "radionuclide" refers to both NARM and reactor-generated byproducts.

On November 16, 1992, Ms. Colgan was being treated for anal carcinoma with a form of radiation therapy called high dose rate brachytherapy at the Indiana Regional Cancer Center. Before the treatment, doctors had placed into her tumor five catheters that were to remain for subsequent treatments. During the treatment, high-intensity radioactive iridium-192 sources were placed sequentially into each of the catheters by a remotely controlled Omnitron 2000 after loader. Iridium-192 is a reactor-generated radionuclide.

At the end of the treatment, radiation therapists believed that the source had been retracted. A radiation monitor in the treatment room indicated that excessive levels of radiation existed, but despite the availability of a portable survey instrument, no one surveyed Ms. Colgan's radiation levels. The staff assumed that the area radiation monitor was malfunctioning, as there had been prior false alarms. The control console of the Omnitron 2000 after loader indicated "safe," leading the staff to believe that the source material not only had been removed from Ms. Colgan's body but also had been fully retracted into the lead shield. Although proper staff radiation safety training and the discrepancy between the monitor alarm and the control panel should have elicited a response, three therapists and Ms. Colgan's attending physician all failed to act. One therapist simply unplugged and reset the monitor. In reality, the wire that connected the iridium-192 source to the catheter had broken, leaving the source in one of the catheters in the patient.

Ms. Colgan returned to her nursing home. On November 20, four days after her treatment, the source-containing catheter came loose and fell out. Nursing home personnel, unaware that the catheter contained radioactive material, placed it in a medical biohazards bag and into storage. Ms. Colgan died the next day, it was later determined, from the radiation misadministration.

Between November 16 and November 25, 1992, residents, employees, and visitors to the nursing home were unknowingly exposed to radiation from the source, first while it was lodged in Ms. Colgan's body and subsequently from within the biohazards bag. Other persons exposed included employees and patients at the cancer center who came near Ms. Colgan during the time she awaited transfer back to the nursing home after her treatment and the ambulance staff who returned her there.

On Friday, November 27, a trailer loaded with medical waste, including waste from Ms. Colgan's nursing home, drove to a medical waste incinerator in Warren, Ohio. At this facility, monitors identified radiation emanating from the trailer. On December 1, a subsequent search identified a name found with the biohazards bag waste and traced it back to Ms. Colgan's nursing home (NRC, 1993).

This unusual case is commonly referred to as the "Indiana, Pennsylvania, incident." Other adverse events involving radiation in medicine are not confined to the loss of byproducts in a patient's body. In the past, errors have been made in the calibration of teletherapy machines that use radioactive cobalt and in the

disposal of those machines and sources. Furthermore, adverse events occur with ionizing radiation in which byproducts play no role at all. Design problems in linear accelerators (another source of radioactive materials and radiation) have led to serious patient overdoses in a limited number of cases because of a failure to measure accurately the output of the machine. In another case, problems with software control of the machines allowed delivery of excessive doses to a few patients.

Furthermore, the occasional adverse event occurs not only during the treatment of cancer. Large doses of ionizing radiation are delivered during diagnosis with fluoroscopy equipment and may cause unnecessary exposure of the operator and the patient. Mistakes may be made in the dosage of diagnostic, systemically administered radionuclides. Beyond this, the quality of radiography may be inferior, necessitating second or third exposures to diagnostic radiation. Such inferior radiography, for example, led first to voluntary and now to congressionally mandated control of the quality of mammography for the detection of breast cancer. Finally, before the advent of byproduct materials and their eventual replacement of most radium sources, there was a long history of the occasional loss of radium sources during brachytherapy.

Such adverse events have the capacity, as demonstrated by the Indiana, Pennsylvania, incident, to overshadow the millions of success stories that result from radiation medicine. The number of favorable outcomes from radiation therapy far exceeds the number of problematic outcomes; good patient outcomes are the norm for most radiation therapy procedures.

As an example, in June 1991, a 30-year-old pregnant woman who was both deaf and mute was diagnosed with a melanoma, which put her in danger of losing her eye. As a photographer, she depended on her vision. Doctors offered her the choice of either removal of her eyeball or insertion of a radioactive iodine-125 ocular plaque. In an effort to save her sight, she underwent placement of the plaque. The plaque delivered 10,000 cGy (centigray) to the apex of the tumor and was removed after 129.2 hours. Because of the shielding of the plaque holding the radioactive source and because of iodine-125's weak emission of gamma rays, most of the radiation emanating from the plaque was absorbed locally, posing no risk of exposure to her fetus or to her health care providers. Four years later, the photographer and her child are alive and well. Her vision is 20/20 on the right and 20/60 on the left.

Another example of success involves a 42-year-old woman who was found to have a carcinoma of the cervix. A hysterectomy was attempted, but because of positive pelvic lymph nodes, the procedure was not completed. She was treated with linear accelerator external beam irradiation followed by an interstitial iridium-192 implant in the cervix, which delivered 3,500 cGy over four days. She has been disease-free for at least two years with normal sexual function and no apparent bowel or bladder complications.

The foregoing discussion of successes and benefits of the uses of radiation in medicine helps to put the Indiana, Pennsylvania, incident in perspective. Nonetheless, that case presents in microcosm many of the complex questions that prompted the IOM study of the NRC's Medical Use Program. Could appropriate public policy have prevented the mishaps that occurred during Ms. Colgan's treatment? Does response to the incident by several federal agencies indicate proper regulatory coverage or regulatory fragmentation and, if the latter, which agency should have taken the lead? Should the federal government have been involved at all, or could a state authority have handled the incident? Would stricter regulations have had any effect, or could regulation instead be loosened without more such mishaps? Indeed, what should be expected from regulations? Can adverse events ever be eliminated entirely? Even the strict regulations, both state and federal, in place in Pennsylvania at the time of this incident did not prevent the human error that caused Ms. Colgan's death.

In sum, the Indiana, Pennsylvania, case crystallized the need for a reexamination of the regulation of radiation medicine. It also led naturally to an examination of radiation safety and the appropriate standards for medical and radiation safety protection practice, including not only the proper education for all health care personnel but also ongoing training that reinforces that education.

THE CURRENT REGULATORY SYSTEM

The NRC Medical Use Program

The NRC, subject to the AEA, is responsible for regulation of nuclear reactors; the regulation of byproduct material used in medicine derives from this broader responsibility.[6] Byproduct material accounts for approximately 10 percent[7] of ionizing radiation procedures used for medical purposes. The NRC's Medical Use Program is a minor part of its regulatory responsibilities; it accounts for about 1 percent of the total NRC budget. More than 80 percent of the time and energy of the NRC's employees—and $512 million of its approximately

[6] The Atomic Energy Commission was originally authorized to regulate nuclear reactors pursuant to the AEA. The NRC, established in 1974, currently has the authority for nuclear reactors.

[7] This percentage of procedures is derived from the information provided in Chapter 2 about procedures in radiation medicine that involve byproduct materials. These data reveal that there are about 800 diagnostic radiology procedures using x-rays per 1,000 population. Thus, more than 200 million x-ray procedures are carried out annually. In radiotherapy, about 500,000 patients are treated with an average of 20 treatments or a total of 10 million treatments. Of these, no more than 20 percent involve byproducts. Eight million nuclear medicine procedures are performed each year, most of which involve byproducts. Thus, of a total of 218 million procedures per year, only 10 million involve byproduct materials, clearly less than 10 percent of the procedures.

$525.6 million budget—is spent regulating nuclear power plants. The overwhelming majority of the NRC's professional staff are not health professionals (the staff's expertise is oriented toward technical and engineering skills). The staff of the Nuclear Medicine Safety and Safeguards division of the NRC has no full-time physicians and presently but one medical consultant.

Until 1946, when Congress first enacted the AEA, virtually all regulation of radioactive material, none of which was reactor-generated, took place at the state level.[8] The AEA provided the Atomic Energy Commission (AEC) authority to regulate possession and use of certain artificial materials for the first time. The AEC's jurisdiction covered radiation and radiation sources (nuclides) produced by nuclear reactors; it did not extend to naturally occurring and accelerator-produced material (NARM) or to machine-produced radiation. The AEA designated the AEC as the agency responsible for establishing a licensing and inspection program for radioactive materials produced in reactors and not used in nuclear weapons or production of electricity.

In 1974, the Energy Reorganization Act split the functions of the AEC in two. Congress determined that it was in the public interest for the AEC licensing and related regulatory functions to be separated from the performance of the other AEC functions, and it created the Nuclear Regulatory Commission to do that job. As part of that job, the NRC is responsible for regulating the medical (diagnostic and therapeutic) use of byproduct materials and protecting the public from undue risks attendant upon their use in health care applications.

Thus, the NRC regulates the medical use of reactor-generated radionuclides under the auspices of a long succession of legislation and regulatory rules that date back about a half century and that include the Agreement State Program established in 1959. Through this program, the NRC discharges its responsibility in two ways: (1) direct regulation of affected institutions (in the case of 21 NRC-regulated or Non-Agreement States), or (2) through formal agreements with state governors (in the case of the remaining 29 Agreement States).[9] The NRC's Medical Use Program, which applies to both the 21 NRC-regulated states and the 29 Agreement States, involves the following responsibilities and activities: (a) registering facilities; (b) registering physicians; (c) annual reporting by each facility; (d) setting criteria for determining misadministration of byproduct materials in medical use; (e) reporting misadministrations promptly; (f) conducting

[8] Public Law 79-585, 60 Stat. 755 (1946).

[9] *Federal Register* (FR) announcement RIN 3150-AC65, on the Quality Management Program and Misadministrations of the NRC Final Rule, indicates that 28 (now 29) states have entered agreements to regulate the use of byproduct material and that they currently issue licenses and otherwise regulate about 4,000 institutions (clinics, hospitals, and physicians in private practice). The NRC directly regulates administration of byproduct material or radiation from such material in 22 (now 21) states, the District of Columbia, the Commonwealth of Puerto Rico, and various territories, for about 2,000 civilian and military hospitals and clinics. See 56 Fed. Reg. (July 25, 1991) at p. 34104.

provider inspections; and (g) applying a system of sanctions for infractions of its regulations.

Two categories of radiation medicine are subject to NRC regulation. The first category is nuclear medicine, which uses radioactive drugs (typically containing very small amounts of radioactive materials) primarily for diagnostic purposes but sometimes for therapy, most often for disease of the thyroid gland. The second is radiation therapy as a primary treatment of cancer. This treatment modality requires much larger amounts of radioactive materials than diagnostic procedures.

Regulation of Other Sources

Because the radiation subject to NRC jurisdiction originates in nuclear reactors, the NRC is called on to regulate only a small portion of the field of radiation medicine. According to 1992 data, about half of approximately 1.1 million new cancer cases were treated with some type of radiation therapy. Of these treatments, sealed sources made from reactor-generated byproduct material were used in no more than 25 percent (Selin, 1993); the other 75 percent of radiation treatments stemmed primarily from external beams of x-rays and electrons produced in linear accelerators, and it included a small number of treatments with charged particles and neutrons. This proportionality within cancer treatments, coupled with the very high proportions of the population receiving diagnostic procedures that do not involve byproducts, shows that a vast portion of the use of radiation in medicine is not regulated by the NRC (as noted earlier and in footnote 7). Assuring the safe use of these preponderant and non-byproduct-related materials has fallen to a wide variety of local, state, and federal agencies; despite attempts at federal coordination, the regulation of these sources is fragmented.

Evolution of Federal and State Regulatory Programs

In 1967 the U.S. Public Health Service established the National Center for Radiologic Health, which later became the Bureau of Radiologic Health (BRH) of the Food and Drug Administration (FDA). By 1968, Congress, realizing that non-byproduct material was not in any way supervised or regulated, passed the Radiation Control for Health Safety (RCHS) act, which established performance standards for devices that emit ionizing radiation. It also directed the Secretary of Health, Education and Welfare to establish and conduct a radiation control program. Although the RCHS act was initially passed in order to control radiation from color television, it included x-ray machines for diagnosis, treatment, research, and education.

In 1976 Congress passed the Medical Device Amendment, under which the Bureau of Medical Devices was established to implement the programs created under the 1968 RCHS Act. In 1982 the BRH and the Bureau of Medical Devices

merged to form the new Center for Devices and Radiologic Health within the FDA. In related activities, the Department of Health and Human Services published in 1985 "Standards for the Accreditation of Education and General Programs for and the Credentialing of Radiologic Personnel." These regulations were not binding except in federal facilities, but they were advisory to the states.

TABLE 1.1 Ionizing Radiation in Medicine

Subject to NRC Regulation	Not Subject to NRC Regulation
Reactor-generated byproduct material	Naturally occurring radioactive material
Reactors	Accelerator-produced radioactive material
	Machine-produced radiation
	X-ray machines
	Particle accelerators
	• Cyclotrons
	• Linear accelerators

While all of this was occurring at the federal level, the states—spurred by (a) the initial Agreement State Program,[10] (b) the need to implement procedures for licensing and regulating the use of ionizing radiation in medicine, and (c) the BRH—voluntarily began to expand their own state radiation health programs. These were usually within the state departments of health. Essentially all the states now have such programs, which are coordinated by the Conference of Radiation Control Program Directors (CRCPD). This group has encouraged the adoption of uniform regulations in the various states and has promulgated regulations that cover all of the uses of ionizing radiation in medicine. Only a portion of the activities of these state programs are federally mandated through the Agreement State Program. The majority of users regulated by the states are involved with other sources of ionizing radiation.

THE INSTITUTE OF MEDICINE STUDY

As described above, the Indiana, Pennsylvania, incident preceded a weeklong series in the Cleveland *Plain Dealer* and was followed by Senator Glenn's announcement that he would begin an investigation into radiation medicine. The Senate Committee on Governmental Affairs held a hearing on the regulation of medical radiation on May 6, 1993, to determine the extent of the NRC's authority and to explore the precautions and measures the states take to protect their citizens. The Senate committee also sought to determine the extent to which federal

[10] Congress amended the AEA in 1959 to establish the Agreement States Program for the regulation and monitoring of the use of byproduct materials. Kentucky became the first Agreement State under this program in 1962.

agencies tracked and recorded the kinds of errors and problems illustrated by the Indiana, Pennsylvania, case.

At the May 6 hearing, Chairman Glenn questioned whether federal and state regulations on medical radiation adequately protected public health and the rights of those who may be put at risk. Although the Cleveland *Plain Dealer* series had triggered this particular hearing, the Senator noted the committee's long-standing interest in the role of federal and state agencies that regulate medical radiation and its concern that regulation of medical radiation was scattered, fragmented, and seriously inconsistent. Ivan Selin, then chairman of the NRC,[11] stated that the NRC had studied the issues of regulatory coverage of all radiation therapy treatment across the country. In response to Senator Glenn's request to expedite the NRC's consideration of these issues, Chairman Selin promised to provide the committee with a preliminary report on medical radiation protection in three months.

After the hearing, an NRC task force was formed, with FDA representation, and it submitted its report to the NRC commissioners on September 15, 1993. That report examined issues and options pertaining to radiation protection of the public health and safety from *all* medical sources of ionizing radiation: machine-produced; NARM; and byproduct material, the only source regulated by the NRC.

The above sequence of events influenced the NRC's decision to seek an external review that would complement an internal management review. According to an internal memorandum the outside study was intended to examine "the basic regulatory rules, policies, practices and procedures to assess whether our current framework for medical use of byproduct material is appropriate to fulfill our statutory responsibilities for public health and safety" (Chilk, 1992). In the winter of 1992–1993, the NRC approached the IOM regarding a study to review and evaluate its Medical Use Program. NRC discussions with IOM senior staff over a period of several months in 1993 led to agreement on the key issues to be examined. The IOM study officially began on January 2, 1994.

The NRC Request to the IOM and the Committee Charge

In its formal request to the IOM to conduct a detailed independent review and make recommendations for needed changes, the NRC defined three major goals:

1. examine the broad policy issues that underlie the regulation of medical uses of radioisotopes (radionuclides);

[11] Ivan Selin resigned his position as chairman of the NRC on March 14, 1995, effective July 1, 1995.

2. study the overall levels of risk associated with the use of ionizing radiation in medicine, assessing (a) the error rates and consequences of the use of byproduct materials in comparison to other medical interventions, and (b) the frequency and consequences of byproduct misadministrations compared to properly conducted administrations; and
3. assess the current statutory or regulatory framework for regulation of the medical uses of byproduct materials.

The NRC also asked that the IOM provide recommendations on two major issues:

1. a uniform national approach to the regulation of ionizing radiation in all medical applications, including consideration of how the regulatory authority and responsibility for medical devices sold in interstate commerce for application of radiation to human beings should be allocated among the federal government agencies and between the federal and state governments; and
2. appropriate criteria for measuring the effectiveness of the regulatory programs to protect public health and safety.

In response to the NRC's request, the IOM appointed a 16-member interdisciplinary committee chaired by Charles E. Putman of Duke University. The committee membership represented a broad range of expertise in the following areas: medicine (diagnostic radiology, nuclear medicine, radiation oncology, and nuclear cardiology); health physics; economics; quality of care; biostatistics; public health; nursing; law; ethics; regulatory matters; and public policy analysis.

In approaching its task, the IOM committee generally accepted the NRC charge as just outlined. The broad policy issues included the adequacy of the 1979 Medical Use Policy Statement and the consistency of NRC regulations and guidance with:

- the extent of the NRC's responsibility to the patient involved in a misadministration, including that of a federal regulatory requirement for patient notification by the physician;
- the appropriate role of the NRC medical consultant and the Medical Use Program; and
- the NRC regulatory policy and whether it could more effectively promote better patient care and safer medical use of radionuclides.

With respect to the third goal, the committee determined that a critical assessment of the current framework for the regulation of the medical uses of byproduct must include the appropriateness of the statutory framework—both federal and state—for regulation of both (a) the medical uses of byproduct material and (b) *other sources* of ionizing radiation used in the medical context. The

committee also noted that the NRC is concerned with the appropriateness of the regulatory relationships that exist among the NRC, the Agreement States, the FDA, and various state boards. Especially important is the complicated relationship between the FDA's Center for Devices and Radiologic Health and the NRC.

Elements of the Study

To carry out its charge, the IOM study committee conducted a series of meetings, held a public hearing, convened a technical panel, commissioned several papers, organized site visits, and sent representatives to relevant professional conferences. Committee meetings, information collected by the staff, and commissioned papers provided essential information about the NRC's Medical Use Program, its origin, and legislative mandate. The committee thoroughly reviewed all available information about the Medical Use Program and had extensive discussions throughout its deliberations about the existing system, the accuracy of data, and the effectiveness of the program.

Meetings

The committee held six meetings, which generally were open to the public; all open sessions were attended by representatives of the sponsor. The first meeting was devoted to organizational matters and planning of the entire study; a briefing by the NRC staff was an integral part of this meeting. Subsequent meetings were concerned with review of background materials, further in-depth briefings by NRC representatives, presentations from outside experts, discussion of issues and information gathered during the various study activities, and early formulation of committee conclusions. The last two meetings were devoted chiefly to discussion of the committee's findings, conclusions, and recommendations and to the production and review of the committee's report.

Public Hearing

In conjunction with the third meeting, the IOM convened a public hearing to clarify issues and to bring in a broad spectrum of experts and interested parties from professional organizations, industry, and the public. One hundred and thirty-nine societies, organizations, and agencies were invited to submit written testimony and to request an opportunity to give an oral statement. They were also asked to share the invitation letter with any other entity that might be interested. The committee received written testimony from 38 organizations, and 15 respondents requested an opportunity for oral presentation at the meeting. Lists of those organizations that were invited to participate, those that presented statements to the committee, and those that submitted written responses can be found in Appendix H.

Technical Panel

One technical panel, which included outside experts and representatives from professional societies, focused on quality of care issues generally and the NRC's "quality management (QM) rule" specifically. Quality of care issues (both processes of care and patient outcomes such as mortality and morbidity) in situations involving radionuclides and in circumstances involving other high-technology diagnostic and therapeutic interventions were discussed at a specially convened meeting (see Appendix I for a list of participants).

Commissioned Papers

The committee commissioned several background or technical papers, to supplement the fact-finding it pursued through workshops and site visits (titles and authors of papers can be found in Appendix J). The topics of these background documents included regulatory issues, risk estimation pertaining to low-level radiation exposure, history of radiation medicine, misadministrations, and perception of risk.

Site Visits

Groups of three or four committee members and one or two IOM staff made four regional site visits to state regulatory agencies and to major facilities or institutions that use radionuclides. Each site visit involved visits to multiple hospital, county, and state offices and meetings with individual practitioners. Two site visits took place in Agreement States (Georgia and California) and two in Non-Agreement States (Minnesota and Massachusetts[12]). The site visits were intended to provide representative information from across the nation, and the data gathered from them are not to be regarded as a systematic or comprehensive basis for quantitative analysis.

Professional Meetings

Attendance by appropriate study staff or committee members at selected professional meetings in 1994 and 1995 provided additional background information and facilitated briefings about the project. Among the specific meetings attended were those of the American College of Nuclear Physicians, American College of Radiology, American Roentgen Ray Society, American Society for Therapeutic Radiology and Oncology, Association of Health Services Research, Association of University Radiologists, Conference of Radiation Control Program Directors, Isotopics, National Council on Radiation Protection and Measurements,

[12] Massachusetts is in the process of becoming an Agreement State.

Radiological Society of North America, Society of Medical Physics, and Society for Nuclear Medicine.

Organization of the Report

The Summary and Chapter 1 of the report provide an overview. Chapters 2 through 4 present essential background material. Chapters 5 and 6 present the committee's analysis, findings, conclusions, and recommendations.

Chapter 2, "Clinical Applications of Ionizing Radiation", surveys the wide array of clinical applications of ionizing radiation, grouping them into diagnostic uses and therapeutic uses. The discussion addresses the types and volume of procedures performed and the institutions and personnel engaged in the use of ionizing radiation medicine. It also describes the form that government control takes with respect to particular sources and uses of ionizing radiation.

Chapter 3, "Regulation and Radiation Medicine", provides a comprehensive account of existing regulation, especially by the NRC and the FDA. It also discusses the history and social goals of regulation; the current regulatory framework, both federal and state; and the direct and indirect costs of regulation to the regulated community.

Chapter 4, "Risks of Ionizing Radiation in Medicine", is a detailed examination of three aspects of the issue of risk: (1) risk assessment as a conceptual and methodological tool applied to radiation medicine; (2) actual and hypothetical risks determined to exist in the use of ionizing radiation in medicine; and (3) the public's perception of risk.

Chapter 5, "Alternative Regulatory Systems", outlines the major alternative regulatory systems developed and considered by the committee and proposes the optimal alternative to supplant the existing regulatory structure. Chapter 6, "Findings, Conclusions, and Recommendations", presents the outcome of the committee's work to Congress, the NRC, and the CRCPD and states.

Scope and Limitations of the Report

All exposure to ionizing radiation has biological effects. Although it is used in industrial as well as medical settings, examining all ionizing radiation regardless of the context is certainly beyond the scope of this committee's charge. Nevertheless, the committee believes that ionizing radiation in all its uses should be scrutinized to determine whether centralizing its regulation is a viable option.

The 1994 General Accounting Office report *Nuclear Health and Safety: Consensus on Acceptable Radiation Risk to the Public Is Lacking* (GAO, 1994) was reviewed by the committee. The report describes the existing federal regulatory regime for radiation as inconsistent, overlapping, and incomplete. After affirming that the GAO assessment of the disjointed federal regulatory system was valid, the committee focused on its more limited charge, turning its attention specifically to ionizing radiation in medicine.

Much of the fractured nature of authority arises from the varied sources of and uses for radiation. This committee, however, sees much more similarity than difference between the subjects of these regulations. The risks of ionizing radiation are determined by the type of particle, energy level, and absorbed dose, not by the nature of the source.

In medicine, both machine-produced radiation and radionuclides (natural and anthropogenic) are used in a variety of tasks, from diagnosis to treatment to research. As far as the patient is concerned, it makes little difference whether the source of the ionizing radiation is natural, a machine, or a reactor byproduct. Thus, protecting patients should be done uniformly and without undue variation solely on the basis of the source of the radiation. Similarly, all worker exposure to ionizing radiation must be scrutinized, regardless of the source.

To be sure, differences exist between x-ray machines and accelerators (which can be shut off) and radioactive materials whether byproducts or accelerator produced. Because radioactive materials continue to generate ionizing radiation before and after treatment is administered, they must be watched carefully during shipment, storage, and disposal as well as during patient treatments. Nevertheless, similarities between the sources are much greater than the differences. At present, however, reactor-generated byproduct materials are much more stringently regulated (at the federal level) than are naturally occurring and accelerator-produced materials (NARM) or machine-produced radiation (regulated at the state level).

The NRC asked the IOM to address the issue of appropriate criteria for measuring the effectiveness of the regulatory programs to protect public health and safety. The task of conceptualizing such criteria is extremely difficult and should not be underestimated. The committee determined that it did not possess the requisite expertise to undertake this task. In addition, those on the committee who were experts in regulation did not believe that the committee would make any headway in this area and recommended that it not be pursued.

The discussion throughout this report focuses on "quality management" as the concept has been defined by the NRC and put into operational form through its QM rule. The committee recognized, however, that issues relating to the measurement and improvement of quality of health care go far beyond this narrow interpretation. Given the complexities of its charge, the committee opted not to examine issues relating to quality assurance in any detail, but it recognized that the NRC's approach was not consistent with contemporary efforts by health care institutions and plans to implement continuous quality improvement programs within their own facilities and by their own practitioners and members.

It was beyond the scope of this committee's study and report to do a full-scale cost-benefit analysis on the medical uses of reactor-generated byproduct materials. Although the committee tried to follow the spirit of cost-benefit analysis, it did not attempt to translate the various effects into dollars. The committee believed recommendations could be made without this difficult step.

Nor did the committee's charge include an examination of the risks associated with various forms of therapeutic and diagnostic treatment of ionizing radiation in medicine. This issue extends beyond the scope and abilities of the committee, especially when considering the inability of the scientific community to come to any consensus on these matters. Furthermore, the committee's charge did not include an examination of the overuse of x-rays and radiation in other procedures. The current federal regulations attempt to address misadministrations, not overuse.

Another consideration was the lack of complete, accurate data regarding the frequency of misadministrations (see Chapter 3). FDA regulations focus on medical device efficacy and devices that malfunction or cause serious injury or death—and not on administration of treatment, physician prescriptions, or other causes of misadministrations (except for the Mammography Quality Standards Act). Misadministration data are not maintained on linear accelerators (only data on serious malfunction of the machine are reported), and consequently there is no way of determining the role of misadministrations with respect to accelerators. Nor are there reliable data to assess the level of risk and effectiveness of regulatory programs for non-byproduct sources of radiation.

Lastly, although this report critically examines several aspects of the NRC's regulatory and enforcement program, the committee recognizes that the NRC is in a very difficult situation. The NRC's programs reflect a federal legislative mandate that requires the NRC to be self-funded through dollars collected for licensure and inspection. This creates an intrinsic conflict of interest for the agency. Another internal conflict arises from the tension between health care providers, who desire latitude to exercise judgment in using radioactive byproduct materials in medicine and freedom from burdensome and detailed reporting procedures, and society and its elected officials, who desire absolute assurance concerning monitoring and safety in the medical use of byproduct radioactive material. These are systemic conflicts over which the NRC has no control.

CHAPTER SUMMARY

Concern is widespread among the states, the Congress, the NRC, and the regulated community that the existing system for regulating radiation medicine needs to be rethought and reformulated. The overarching question on the part of the IOM committee was whether the scientific data on risks from radiation medicine justify the extensive regulatory system for byproduct materials currently in place, particularly when compared with the regulatory systems imposed upon non-byproduct radiation and on other modalities of medical care.

Use of ionizing radiation in medicine, termed "radiation medicine" in the generic sense in this report, is extremely widespread, and it is of great benefit in the diagnosis and treatment of disease. It is also unevenly regulated. The hazards associated with the use of ionizing radiation must be balanced against both the

benefits to the health of the population and the costs of regulation to society. The number of lethal or highly morbid adverse events appears to be small, at least as can be determined from the available information. The findings of the committee point to the need for improved databases on the actual incidence of adverse events and severe misadministrations.

The apparent low incidence of adverse events suggests that the stringent NRC regulation of the practice of medicine may not be warranted. It is clear, however, that all uses of ionizing radiation call for some level of regulation and that this regulation needs to be made more consistent and coordinated. To date the federal role has been uneven and divided; much of the current supervision of educational requirements in the use of ionizing radiation, other than the minority of incidents in which byproduct material is used in Non-Agreement States, falls to the states themselves. The chapters that follow give in detail the basis for these introductory observations and make recommendations as to ways in which the regulation of ionizing radiation in medicine may be made more uniform and more responsive to the actual risks involved.

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2

Clinical Applications of Ionizing Radiation

This chapter provides an overview of the wide array of clinical applications of ionizing radiation. As is customary, applications are grouped here into diagnostic and therapeutic uses. These two categories are further divided by whether the ionizing radiation is administered through external or internal sources.

Also of importance for understanding this area of medicine are the many different medical conditions for which these clinical applications are critical and the levels of exposure to radiation involved in each procedure. This last information is important because the known or perceived risks from these clinical applications are related directly to exposure levels. It is against these risks that government regulation is primarily aimed. Thus, this chapter also discusses the forms that government control takes over the various sources and uses of ionizing radiation. As will become apparent to the reader, the divisions of regulatory authority do not clearly correspond to the risks associated with the sources and applications.

As an aid to the reader, Table 2.1 provides a chart of radiation sources and their applications. In addition, a preliminary section introduces some terminology about how levels of radiation are customarily denoted. The following two main sections of the chapter discuss in turn the diagnostic and the therapeutic applications of ionizing radiation. These sections are followed by the chapter's conclusion.

MEASURES OF PATIENT EXPOSURE TO IONIZING RADIATION

Initial systematic studies of patient exposure, beginning in the 1970s, used an index called "entrance skin exposure" in units of milliroentgen (mR). Since

TABLE 2.1 Radiation in Medicine

		Applications	
Radiation Source	Origin	Diagnostic	Therapeutic
Ioninzing Radiation[a]			
Radioactive Materials			
Reactor-generated byproduct material	**Nuclear reactors**	**Nuclear medicine (radiopharmaceuticals[b])**	Nuclear medicine (radiopharmaceuticals[b]) **Teletherapy (Sealed sources) Brachytherapy (sealed sources)**
Radium	Naturally occurring		Brachytherapy
Accelerator-generated radionuclides	Particle accelerators (linear accelerators, cyclotrons)	Nuclear medicine (radiopharmaceuticals)	Nuclear medicine (radiopharmaceuticals); Brachytherapy (sealed sources)
Machine-Produced Radiation[c]			
X-radiation	X-ray machines	Radiography Fluoroscopy Computed tomography Dental x-rays	External beam x-ray therapy

High-energy particle radiation	Particle accelerators (linear accelerators, cyclotrons)		Electron, neutron, and positive ion therapy
High-energy particle radiation	**Nuclear reactors**		**Boron neutron capture therapy**
Nonionizing Radiation[d]			
	Magnetic resonance imaging (MRI) machine	MRI scan	
	Ultrasound	Ultrasound scan	

NOTE: Sources or machines indicated in **bold** are subject to NRC regulation. All others may be regulated at the state level.

[a] Scope of Institute of Medicine study.

[b] Also subject to regulation by the Center for Drug Evaluation and Research and/or the Center for Biologics Evaluation and Research of the Food and Drug Administration (FDA).

[c] All devices are subject to regulation by the FDA's Center for Devices and Radiological Health.

[d] Uses of nonionizing radiation are included here for illustrative purposes only; they are not within the scope of this study.

that time, the metrics used in science and medicine have changed to internationally accepted units, and the relevant index in radiology is now "entrance skin air kerma" (ESK) in units of milligray (mGy). An entrance skin exposure of 100 mR is equivalent to an ESK of 0.869 mGy; both measures quantify the intensity of x-rays in air at the patient's skin.

To calculate a patient's radiation dose for a specific organ for a given ESK, radiologists must consider both the attenuation and the scattering of the x-ray within the patient. To help in this process, the Food and Drug Administration (FDA) of the Department of Health and Human Services and others have published tables and computer codes that give the dose to various organs per unit ESK for many different radiographic procedures. To estimate patient risk or to compare a nonuniform exposure to whole body exposure, the International Commission on Radiological Protection recommends that individual organ doses be converted to "effective dose equivalent" (EDE) in units of millisievert (mSv).[1] EDE is the dose that, if delivered uniformly, would have the same biological effect as the actual (nonuniform) dose. It is calculated as the product of individual organ dose and an "organ weighting factor" given by the International Commission on Radiological Protection.

Collective dose equivalent is the product of EDE and the number of persons receiving a radiation dose; it is expressed in units of person-sievert (person-Sv). Collective dose equivalent for diagnostic medical x-rays, for example, can be estimated as the product of the EDE per procedure and the total number of procedures.

Collective dose equivalent is of interest in terms of broad population exposure to radiation overall and to radiation from various medical uses. If medical uses produced a very high exposure compared to the exposure levels encountered in ordinary daily activities, policymakers and others might have reason to direct relatively more attention to the regulation of medical uses of ionizing radiation. Conversely, if it is the case that common daily activities expose the general population to radiation levels significantly far in excess of those from medical applications, policymakers might have less reason or interest in such regulation.

The discussions that follow present information on radiation exposure from various procedures in some depth, with the aim of providing the reader with a sense of the inherent risk (or lack of it) of various techniques that use ionizing radiation. These interventions are by no means the only source of exposure to radiation in this country, however. Normal background radiation from all natural sources (including radon) in the United States exposes each member of the population to an average EDE of about 3 mSv per year.

[1] The earlier unit was millirem (mrem); 1 mSv = 100 mrem.

DIAGNOSTIC APPLICATIONS OF IONIZING RADIATION

The diagnostic uses of ionizing radiation are classified below under two basic headings: radiology and nuclear medicine. In radiology, the radiation administered is external to the patient; in nuclear medicine, it is internal. The discussion of each of these two classes of applications addresses types of procedures, utilization, radiation doses, and radiation regulation and control.

External Sources: Radiology

Types of Procedures

In the 100 years since the discovery of x-rays, diagnostic radiology has grown from a scientific curiosity to a pervasive and essential part of modern health care. Radiology originated with the use of ionizing radiation to diagnose human disease. The development of nonionizing technologies, such as ultrasound and magnetic resonance imaging (MRI), has led to the more generic term "medical imaging." Indeed, the fastest growing areas of radiology are these two nonionizing modalities. Nevertheless, x-ray imaging continues to comprise 80 to 90 percent of all imaging procedures. It is performed using three different imaging techniques: radiographic imaging, fluoroscopic imaging, and computed tomography (CT).

The physical principle underlying x-ray imaging is the partial transmission of x-rays through the body. An external source produces x-rays, and this radiation interacts with tissues in the patient's body either through absorption or scattering. The degree of interaction depends on various factors (such as the energy of the x-rays and the density of tissues traversed). The three main imaging techniques rely on different mechanisms for detecting, viewing, or recording the x-rays emerging from the patient's body.[2] In all cases, however, the essential interaction

[2] In radiographic imaging, the x-rays emerging from the patient are detected by a cassette containing a sheet of film sandwiched between fluorescent intensifying screens. The resulting radiographic image may be thought of as a two-dimensional map of the differential attenuation of x-rays passing through the body. For fluoroscopic imaging, transmitted radiation is detected by an x-ray image intensifier. Radiologists may use a television pickup tube or a 35-millimeter (mm) cine camera to view the resultant image or, for very common procedures, observe the dynamic image on a closed-circuit television monitor. Selected still images may also be obtained. CT imaging relies on x-ray transmission confined to a narrow (1 to 10 mm) strip. Transmitted x-rays are detected by a scintillation or solid-state radiation detector. By rotating the x-ray source around the patient and taking thousands of transmission measurements at many different angles, a digital image can be reconstructed of a tomographic or cross-sectional "slice" of the patient without anatomical structures superimposed upon one another. In a typical procedure, 10 to 50 adjacent slices are obtained. CT images are much sharper than conventional film-screen images because scatter radiation is eliminated, comparatively high doses of radiation are used, and a narrow range of gray shades can be displayed.

of x-rays with tissue produces an unwanted, but unavoidable, consequence, namely the deposit of some radiation dose in the patient.

The vast majority of x-ray procedures are performed by radiographic imaging. These radiographic imaging procedures are in turn typically divided into what are considered "conventional" examinations, on the one hand, and "contrast studies," on the other.

Conventional examinations. Most notable among the conventional examinations is chest radiography, the most common of all radiographic imaging procedures. It is widely available (even at bedside, using portable x-ray machines), low in cost, and conveniently repeated to assess clinical changes. It is a primary tool in the diagnosis of diseases of the lungs (particularly infectious disease and cancer); it provides information on midline anatomical structures and the cardiovascular system (e.g., for diagnosing congestive heart failure); and it is useful for monitoring the status of critically ill patients. At times, chest radiography has been used ineffectively and inappropriately (e.g., for certain screening or administratively required examinations or for routine hospital admission). To reduce unnecessary utilization, professional organizations have established standards for its performance. Chest radiography may undergo technological modification in the future, such as the use of digital image receptors, but it will likely remain the most prevalent imaging examination.

Other conventional examinations include those of the extremities, spine, skull, abdomen, pelvis, and breast. Radiographic views of the extremities are the most efficient way to diagnose broken bones and injured joints, but radiographic imaging is now less common than before for several other parts of the body. For example, CT and MRI examinations have largely replaced radiographic imaging of the spine and skull for central nervous system evaluation, and body CT and ultrasound have somewhat reduced the use of conventional radiographic examinations of the abdomen and pelvis.

Mammography is an example of a radiographic imaging procedure that now plays a critical role in the diagnosis of a major health problem in this nation. It has undergone dramatic improvement in image quality and reduction in patient dose, and the development of units dedicated exclusively to mammography has optimized the total radiographic system (from x-ray tube to film-screen cassette) for breast imaging. The consequences of these technological advances are significant. For example, in women older than 50 years of age, screening mammography is the best method for early detection of breast cancer. As part of a comprehensive program of screening, follow-up, and treatment, mammography can be expected to yield a 30 to 50 percent reduction in breast cancer mortality (Feig, 1995; Tabar et al., 1995).

Contrast studies. Contrast studies are a wide range of radiographic imaging studies in which the patient is administered an agent to improve contrast in the x-ray image. For example, patients ingest or are injected with compounds containing barium (oral) or iodine (oral and intravenous) or with low-density agents such as air. Contrast agents have been used in imaging of the alimentary tract (upper gastrointestinal (UGI) series and barium enema), the urinary tract (intravenous pyelogram), the gall bladder (oral cholecystogram), and the spinal cord (myelogram).

The frequency of contrast studies decreased from 1970 to 1980, as competing techniques (e.g., endoscopy and colonscopy for alimentary tract evaluation, ultrasound and CT for body evaluation, and CT for central nervous system evaluation) became available. The advent of MRI in the 1980s accelerated this decrease. In general, the trend away from contrast studies can be attributed to various technological, medical, and economic factors, such as improved diagnostic accuracy, reduced risk of medical complications, and the changing content of various physician specialties. For instance, myelography is much less frequently performed because MRI yields superior images and requires no needle puncture of the spinal canal. As another example, although the double-contrast UGI series yields diagnostic results and clinical outcomes nearly identical to those of endoscopy at one-third the cost, endoscopy has largely supplanted the UGI series in many institutions, in part owing to the establishment of gastroenterology as a procedure-oriented subspecialty.

Another form of contrast study is the "special"[3] or intravascular procedure. Here, a catheter is introduced into an artery or vein and directed to an area of interest. Once in position, an iodinated contrast agent is injected into the catheter while many images (tens to hundreds) are rapidly obtained. In many instances, radiologists perform a subtraction study, in which an image with contrast agent present is subtracted from an identical image without contrast to yield an image of just the vascular anatomy.

There are several variations of these special procedures. Cerebral angiography is performed to evaluate conditions such as vascular obstructive disease,

[3] "Interventional procedures" seek to treat disease by anatomic manipulation or drug delivery, through a fluoroscopically guided intravascular catheter. Although interventional procedures are therapeutic applications rather than diagnostic, they are mentioned here because they evolved from special procedures. In percutaneous transluminal angioplasty, a small balloon-tipped catheter is used to open blocked arteries mechanically. The analogous procedure for the coronary arteries in the heart is called percutaneous transluminal coronary angioplasty. Other types of catheters, which use heat rather than expansion to open blockages, also are available. Intraluminal thrombolytic therapy uses selective catheterization to deliver clot-dissolving drugs directly to the site of vascular obstruction. Traumatic or congenital bleeding can be treated by embolotherapy, by introducing an artificial clot-forming material, such as surgical gelatin foam, into the specific site of the bleeding.

aneurysm, arteriovenous malformation, and brain tumor. Visceral and peripheral angiography studies are performed to evaluate obstructions and aneurysms in the vascular system. Cardiovascular procedures are done to measure heart functional capacity and to assess coronary artery obstruction.

TABLE 2.2 Relative Frequency and Absolute Utilization Rate of Radiological Procedures in 1980

Examination	Relative Frequency (%)	Rate per 1,000 Population
Skull	2.6	20.8
Other head and neck	1.9	15.5
Cervical spine	2.8	22.6
Head CT	1.5	11.9
Body CT	0.3	2.7
Chest	35.3	283.2
Mammogram	0.7	5.8
Abdomen	1.9	15.0
Biliary	4.4	35.0
Thoracic spine	1.0	8.0
Lumbar spine	7.1	57.1
Full spine	0.8	6.2
Upper gastrointestinal	4.2	33.6
Barium enema	2.7	21.7
Pyelogram	2.3	18.6
Pelvis	2.6	20.8
Extremity	24.8	199.1
Special vascular procedure	0.6	4.4
Cardiac catheterization	0.3	2.2
Other	2.2	17.3
Total	100.0	801.5

SOURCE: Summaries presented in National Council on Radiation Protection Report 100 (NCRP), 1989.

Utilization Rates

The most recent detailed data about the rates of use of radiological diagnostic procedures date to work by the National Council of Radiation Protection (NCRP) for 1980 (NCRP, 1989), as presented in Table 2.2. As these data indicate, the chest x-ray examination is by far the most common procedure (accounting for over one-third of all procedures tabulated); it is followed by examinations of the extremities (about one-quarter) and of the spine (thoracic, lumbar and full, adding to about one-tenth).

TABLE 2.3 Total Number (in thousands) of Imaging Procedures in U.S. Hospitals, 1970–1990

Procedure	1970	1980	1990
General radiology	81,700	133,132	179,063
Computed tomography (CT)	0	2,931	13,394
Ultrasound	200	5,177	11,815
Magnetic resonance imaging	0	0	1,874
Total	81,900	141,240	206,146

NOTE: General radiology includes all x-ray procedures except CT. SOURCES: Johnson and Abernathy, 1983; NCRP, 1989; Sunshine et al., 1991; Mettler et al., 1993.

Although broad-based data are sparse at best, the total numbers of procedures and rates per 1,000 population have certainly increased in the intervening years. In addition, the relative distribution among types of procedures has undoubtedly changed in response to new imaging modalities and shifts in the settings in which radiological examinations are done.

In 1980, approximately 80 to 85 percent of all radiological procedures were estimated to have been performed in hospitals (for both inpatients and outpatients), and the remaining 15 to 20 percent were done in physician offices or outpatient imaging centers. By 1990, approximately 25 to 35 percent of all imaging procedures were estimated to occur outside of hospitals (Sunshine et al., 1991). The trend towards nonhospital-based imaging has accelerated since 1990, as health care providers have reacted to market and reimbursement forces by moving imaging procedures outside the hospital setting.

No studies have updated the distribution of procedures at the level of detail reflected in Table 2.2 Some more recent information on specific diagnostic modalities is available, however. The frequency of CT use has greatly increased, from about 2 percent of radiological procedures (excluding ultrasound and MRI) in 1980 to about 7 percent in 1990. The rates of some procedures, such as plain films of the skull or lumbar spine and contrast studies of the GI tract, have probably decreased.

Over the years, several agencies, associations, and individuals have developed data on the total volume of imaging procedures. These include the FDA, the NCRP, and the American College of Radiology (ACR) (see Johnson and Abernathy, 1983; NCRP, 1989; Sunshine et al., 1991; Mettler et al., 1993). Since the compilation of the information presented in Table 2.2, less detailed surveys (which have not broken down rates for specific imaging procedures) have been published. Table 2.3 gives information for hospital-based procedures for 1970, 1980, and 1990. In this 20-year period, the total number of imaging procedures in hospitals rose by two and a half times, from just under 82 million

procedures to more than 206 million, with a steep growth rate in the use of CT, ultrasound, and MRI.

TABLE 2.4 Estimated Total Number of All Medical Imaging Procedures, 1970–1990

Year	No. of Procedures	Total U.S. Population	Rate per 1,000 population
1970	136,000,000	204,000,000	670
1980	181,000,000	226,000,000	800
1990	294,000,000	249,000,000	1,180

NOTE: Procedures include nonionizing technologies (ultrasound and magnetic resonance imaging).
SOURCES: Johnson and Abernathy, 1983; NCRP, 1989; Sunshine et al., 1991; Mettler et al., 1993.

The upward trend in the overall use of diagnostic radiology procedures, including both those provided in hospitals and those provided in nonhospital settings such as physician offices and freestanding centers, is slightly smaller in percentage terms but dramatic nonetheless. Data in Table 2.4 indicate that the total number of procedures more than doubled, from 136 million to 294 million, between 1970 and 1990, resulting in rates per 1,000 persons of 670 and 1,180, respectively. While the total utilization rate of all imaging procedures per 1,000 population grew 48 percent from 1980 to 1990, rates of procedures that expose patients to ionizing radiation rose only about 28 percent. The 1990 figures cited here are based on fairly crude estimates, but they are the best available at this time. No work has been published in recent years to assess the impact of managed care or other cost-containment strategies on the use of diagnostic radiology services.

It should be emphasized that the charge to the committee was to assess the Nuclear Regulatory Commission's (NRC's) Medical Use Program and problems related to misadministrations. Consequently, the committee did not examine the overuse of radiation in medicine, which is probably best addressed by professional training and patient advocacy.

Radiation Doses

Radiation dose and the immediate or short-term adverse consequences of diagnostic radiology procedures are of concern to the health care professions, the public, and regulators. Radiation dose depends on numerous factors, including the size of the patient, the radiation sensitivity of the image receptor, the energy of the x-ray beam, the radiation exposure rate, and the total time the x-ray tube is energized. Because exposure of both individual patients and populations is of concern, measurements are taken for both person-specific exposure (e.g., ESK and EDE, see above) and collective dose equivalent.

TABLE 2.5 Typical Entrance Skin Air Kerma (ESK) per Procedure and Typical Effective Dose Equivalent (EDE) for Several Common Procedures

Procedure/View	Average ESK per Image[a]	Average EDE per Procedure[b]	EDE Level as % of Background Radiation
Chest		0.08(8)	3
AP	0.23(27)		
LAT	0.70(80)		
Skull		0.22(22)	7
AP	4.17(480)		
LAT	2.46(283)		
Cervical spine		0.20(20)	7
AP	2.26(260)		
LAT	1.48(170)		
Lumbar spine		1.27(127)	42
AP	7.68(884)		
LAT	27.8(3,200)		
Abdomen		0.56(56)	19
AP	5.76(663)		
LAT	18.25(2,100)		
Upper gastrointestinal		1.08	36
Fluoro (rate per minute)	17.38(2,000)		
Spot film	7.35(846)		
Head computed tomography		1.11	37
10-mm slice	44(5,063)		
Mammogram		0.06(6)	2
Craniocaudal	1.28(128)[c]		
Extremities		0.01	0.3
Hand/foot	0.09(10)		

NOTE: A given procedure usually consists of two or more films. AP = Anterior/posterior. LAT = Lateral view. SOURCES: NCRP, 1989; Suleiman et al., 1991; et al., 1992.

[a] In units of milligray (mGy); figures in parentheses are the equivalent "entrance skin exposure" measure in units of milliroentgen (mR).

[b] In units of millisievert (mSv); figures in parentheses are the equivalent in millirem (mrem).

[c] Mean glandular dose.

Patient-specific radiation dose. Table 2.5 provides, for several common imaging procedures, comparative information related to some of these factors: the average ESK per image, the average EDE per procedure (which can include multiple images), and the level of EDE from the procedure, expressed as a percentage of background radiation.

Although extensive surveys have not been done since the early 1980s, experts believe that in the 1990s, the EDE of some of these diagnostic procedures may be lower than the figures given in Table 2.5.[4] Better technology (e.g., wider use of highly sensitive rare-earth phosphor intensifying screens) explains the reduction. For example, Rueter et al. (1992) report that surveys conducted in 1973, 1981, and 1987 showed, respectively, an average anterior/posterior lumbar spine ESK of 6.55, 5.57, and 3.65 mGy; the entrance exposure dropped by 35 percent from 1981 to 1987 and was almost half of the 1973 value. Values for chest radiography did not decrease as dramatically.

Unlike conventional fluoroscopic procedures such as the UGI or barium enema (with typical exposure times of less than 5 minutes), special and interventional procedures can involve long exposure times (20 minutes or more), prompting additional concern about radiation dose. Some experts are also wary of fluoroscopic equipment that is operated in a high radiation output mode in order to reduce noise and improve image quality for catheter placement (Cagnon et al., 1991). Several instances have been reported of high skin doses of several hundred rem resulting in acute effects such as radiation burns and hair loss. Professional societies, the FDA, and equipment manufacturers have taken steps to address these problems (ACR, 1992).

Collective dose. The NCRP developed an estimate of collective dose equivalent for x-ray procedures in 1980, the last year sufficient data were available for accurate calculation (Edwards, 1995). In that year, the total collective effective dose to the U.S. population (average EDE per procedure times total number of procedures) was 92,000 person-Sv, or about 0.40 mSv per person. This is not an especially high rate, compared to natural background radiation levels in this country of 3 mSv per person. It implies that x-ray diagnostic imaging adds about 13 percent to the radiation dose for the general population that comes solely from our daily environment.

These figures might be used to calculate the potential risk of death from radiation exposure. However, the NCRP noted that if this collective dose were

[4] The data in Table 2.5 are taken from *NCRP Report 100: Exposure of the U.S. Population from Diagnostic Radiation* (1989), and are based on surveys conducted in the late 1970s and early 1980s by the FDA's Center for Devices and Radiological Health. They represent institutional averages obtained with standard phantoms (except the UGI data, which were obtained from actual patient procedures). Individual exposures can be quite different, depending on actual patient size, technique factors, image receptor speed, and film processing conditions. For this reason, the Joint Commission for Accreditation of Healthcare Organizations requires that typical patient exposures be measured for each institution. Taken as a broad overview, however, it is evident that, even for procedures having high entrance exposure, the effective dose equivalent for most diagnostic procedures is quite low. This is because a given imaging procedure irradiates only a few organ systems, and organ dose is much lower than entrance skin dose.

used to estimate mortality risks, the resulting figure would overestimate actual risk. Risk coefficients (fatalities per person-Sv) assume a population at risk identical in age, sex, and other characteristics to the U.S. population as a whole. These assumptions are faulty, however, for several reasons. Older people, for instance, who are more likely to receive medical x-rays, are generally beyond child-bearing age. In addition, the latency period for certain cancers may be greater than the average life expectancy of these older age groups. When these factors are taken into account, in a "weighted" collective dose equivalent, the per-person figure (for 1980) decreases from 0.40 mSv to about 0.25 mSv, which is less than 10 percent more than the typical background levels of exposure for the U.S. population.

No precise collective dose estimates have been published for 1990. If one assumed that EDE per procedure and the relative frequencies of procedures performed did not change, then collective dose equivalent would track utilization directly. From 1980 to 1990, the total number of x-ray procedures rose about 40 percent while the population increased 10 percent. These figures yield crude estimates of an annual collective dose of 129,000 person-Sv and a per-person EDE of 0.52 mSv.

These last values are probably overestimates, however, for two reasons. The relative frequency of some x-ray procedures (such as those for the skull and alimentary tract) that deliver relatively higher doses has probably remained the same or decreased. Furthermore, higher speed image receptors are more prevalent. Studies using very high dose radiation, such as special and interventional procedures, have not been included in this estimate, but they may not have a great impact because of their relatively low utilization rates.

Radiation Regulation and Control

Control and regulation of diagnostic x-rays are divided among local, state, and federal agencies. Qualifications and training of physicians and equipment operators are usually regulated by state, rather than federal, law. State standards are far from uniform. Although x-ray equipment manufacture is controlled by federal statute, public and occupational exposures are regulated by state statute. Thus, states regulate the medical uses of x-rays, from simple chest x-rays to cerebral angiography.

An exception to the generally laissez-faire attitude of the federal government toward clinical diagnostic imaging is mammography. The Mammography Quality Standards Act, effective in 1994, sets forth very detailed federal statutes for the regulation of the approximately 11,000 mammography centers in the United States. Part 900 of Title 21 of the Code of Federal Regulations (CFR) sets criteria for physician residency training in mammography and for subsequent continuing medical education; minimum film interpretation work loads; and equipment performance, calibration, and quality assurance standards. The law also

requires annual inspections of each facility to assure compliance. No similar federal programs exist for other areas of diagnostic imaging.

No law directly limits the total amount of radiation received by an individual patient in the course of a medical procedure. The decision to recommend a diagnostic or interventional procedure involves medical judgment concerning the radiation risks (and other risks, such as reaction to contrast agents), compared with the medical benefits as they apply to the unique circumstances of individual patients. An increased chance of cancer associated with even a high dose neurointerventional procedure is well justified if the alternative is failure to control intracranial bleeding. Conversely, the extremely low excess risk associated with a chest radiograph is unwarranted if there is no medical reason to perform the procedure. Although it is inappropriate (and probably impossible) to control patient exposure through legally imposed patient dose limits, control of professional standards, qualifications, and training does have a direct impact on patient dose.

Manufacture and installation of medical x-ray equipment are regulated by the FDA, through 21 CFR Part 1020. These regulations, which apply to radiographic, fluoroscopic, and CT equipment sold in the United States, set equipment performance standards for items such as tube housing leakage, beam filtration, beam collimation, accuracy and reproducibility of technique factors, and fluoroscopic exposure rates. Equipment installers supply certificates of compliance to the FDA for all newly installed equipment. These reports also are used by the states as a means of registering new equipment for state radiation control programs.

Medical x-ray safety of the public and occupationally exposed workers is controlled by the states. Dose limits and other regulations set by the NRC for medical use of byproduct material do not apply to x-ray sources. However, the Occupational Health and Safety Administration sets similar dose limits for workers not covered by NRC regulations. The Conference of Radiation Control Program Directors maintains a standing committee to produce a uniform set of suggested regulations. These *Suggested State Regulations for Control of Radiation* are used by state departments of radiological health as guidance for formulation of state law. Local governments at the county and city level sometimes impose additional regulations on occupational exposure and medical x-ray equipment.

Internal Sources: Diagnostic Nuclear Medicine

Types of Procedures

Nuclear medicine is the medical and laboratory specialty that employs the nuclear properties of radioactive and stable nuclides to evaluate metabolic, physiologic, and pathologic conditions of the body. Relying on an ever-growing number of radiopharmaceuticals (pharmaceuticals marked with a radioactive

agent so that they may be traced), nuclear medicine laboratories perform a host of diagnostic procedures, including studies of the thyroid, cardiac system, liver, kidney, lung, and gastrointestinal systems, as well as studies of mineral metabolism and the entire body.

Nuclear imaging. In nuclear imaging, clinicians either inject small amounts of radiopharmaceuticals into patients intravenously or have patients inhale or ingest the material. Depending on the metabolic pathways of the pharmaceutical in question and disease status of the patient to be studied, the radiopharmaceutical is distributed nonuniformly throughout the body. Gamma rays emitted from these locations escape the body and are imaged by means of a position-sensitive scintillation detector, commonly called a gamma camera.

The efficacy of such studies depends on the tracer principle and on the ability to detect many of the radioactive agents used without disturbing the anatomic system under study. The tracer principle is that very small amounts of materials with particular chemical and physical identities will follow natural physical and biochemical pathways and allow detection instruments to sense the radioactivity from outside the patient. Detectors range from probes that are aimed at a particular part of the patient to extremely sophisticated instruments that compute three-dimensional images of distributions of radioactivity in the patient.

Compared with other imaging technologies such as radiography and CT, discussed above, standard gamma cameras produce considerably less sharp images. This lower resolution of nuclear medicine images is not a major drawback, however, because the clinical utility of nuclear medicine imaging stems primarily from its ability to assess physiologic function rather than anatomy. That is, clinicians pay particular attention to detection and measurement of abnormal organ function rather than to altered organ structure.

Tracer compounds are usually labeled with technetium-99m (Tc-99m), a radionuclide that decays with a 6-hour half-life, but other agents are also used. Among the more common are thallium-201 (Tl-201), xenon-133 (Xe-133), iodine-123 (I-123), iodine-131 (I-131), and gallium-67 (Ga-67).

Used alone or in combination, these nuclides enable diagnosis of a multitude of conditions. These include coronary artery disease (a decrease in blood supply to the heart caused by the narrowing of the blood vessels), pulmonary embolism (a life-threatening blockage of lung blood flow), thyroid carcinoma, brain disorders, acute cholecystitis (an inflammation of the gall bladder), gastrointestinal bleeding, renal artery stenosis (a frequent cause of elevated blood pressure), bone cancer, and even acute fevers of unknown origin. This list is but a small sample. The diagnoses arrived at through nuclear medicine not only name the illness, but also allow physicians to make complicated decisions, such as when stop chemotherapy that is damaging heart muscle, how to plan surgery before removal of lung segments, when to treat a patient for Cushing's syndrome

(hypercortisolism) as opposed to Conn's syndrome (hyperaldosteronism), and whether to ready a patient's family for the onset of Alzheimer's disease.

TABLE 2.6 Properties of Radionuclides Used in Common Nuclear Medicine Procedures

Radionuclide	Symbol	Half-Life
Oxygen-15	O-15	2 min
Nitrogen-13	N-13	10 min
Carbon-11	C-11	20 min
Fluorine-18	F-18	1.8 hr
Technetium-99m	Tc-99m	6 hr
Iodine-123	I-123	13 hr
Indium-111	In-111	2.8 days
Thallium-201	Tl-201	3 days
Gallium-67	Ga-67	3.1 days
Xenon-133	Xe-133	5.3 days
Iodine-131	I-131	8 days

Current trends in clinical nuclear medicine include an emphasis on radioimmunodiagnosis, single photon emission computed tomography (SPECT), and positron emission tomography (PET). In radioimmunodiagnosis, newly developed monoclonal antibodies are used to detect a variety of cancers and to trace myocardial infarction. SPECT and PET are techniques that offer the special advantages of cross-sectional imaging, analogous to x-ray computed tomography. SPECT is already widely applied as a major improvement of nuclear imaging. PET has very special advantages for sensitivity and resolution as well as significant potential for the evolution of new, physiologically important tracers. For full implementation of the PET method, a high-energy accelerator (cyclotron) is required to produce short-lived nuclides that decay by positron emission. PET is now available in many major centers, but it has not yet diffused to community hospitals.

Radionuclides and radiopharmaceuticals. Radiopharmaceuticals used for nuclear medicine imaging are categorized by the radionuclide and the pharmaceutical to which it is bound. The physical characteristics of the radiopharmaceutical (which include photon energy, physical half-life, and particulate decay products) are determined by the radionuclide, whereas physiological properties (such as uptake site, metabolism, and biological half-life) are determined by the pharmaceutical.

Half-life is a particularly important issue for the exposure of patients (and others) to radiation, because as half-life decreases, a greater fraction of the total decay occurs during the image acquisition. For example, the ideal radionuclide for imaging with a gamma camera (a) decays with the emission of only gamma rays (to reduce patient dose), (b) has a low gamma ray energy (to escape from

the patient, yet still be detected with high efficiency and high intrinsic resolution by the gamma camera), and (c) decays with a physical half-life on the order of minutes to hours.[5] Table 2.6 summarizes the half-life properties of radionuclides commonly used for nuclear medicine imaging. As seen there, the half-life ranges from 2 minutes (oxygen-15) to 8 days (iodine-131). Approximately 85 percent of nuclear medicine imaging studies are performed with pharmaceuticals labeled with Tc-99m, which has a half-life of 6 hours. The physical properties of this isotope closely approximate those of the ideal radionuclide.

TABLE 2.7 Number of Nuclear Medicine Procedures (in thousands) by Examination Type

Examination	1972	1982	1993
Brain	1,250	812	900
Hepatobiliary	26	179	198
Liver	455	1,424	1,578
Bone	81	1,811	2,007
Respiratory	322	1,191	1,320
Thyroid	356	677	750
Renal	108	236	262
Tumor	10	121	134
Cardiovascular	25	950	1,053
Other	406	—	—
Total	3,039	7,401	8,202

SOURCES: NCRP, 1989; NRC, 1994.

Utilization Rates

The total numbers of nuclear medicine procedures are available for the past 20 years from various sources. Table 2.7 provides annual counts of several nuclear medicine procedures in various body systems for 1972, 1982, and 1993. As can be seen, in 1993, the total number of procedures exceeded 8 million. In the 20-year period, the number of bone imaging procedures increased dramatically, as did those on the cardiovascular system; conversely, brain imaging procedures dropped.

[5] Although not related to clinical efficacy, an added benefit of a short physical half-life is that it eliminates problems of low-level radioactive waste disposal, because contaminated hospital supplies can be "decayed in storage" and then disposed of as normal waste.

TABLE 2.8 Dosage Levels for Several Nuclear Medicine Procedures

Procedure/Radio-pharmaceutical	Administered Activity (MBq)	Maximally Exposed Organ	Organ Dose (mGy)	EDE (mSv)	EDE Level as % of Background Radiation
Bone scan (Tc-99m phosphate)	740.0	Bladder wall	44	4.4	147
Thyroid scan (Tc-99m pertechnetate)	185.0	Stomach wall	13	2.0	67
Thyroid scan (I-131 sodium iodine)	3.7	Thyroid	1,960	59.0	1,967
Thyroid scan (I-123 sodium iodine)	11.0	Thyroid	171	0.2	7
Static renal (I-131 Hippuran)	9.0	Thyroid	95	0.5	17
Dynamic renal (Tc-99m DTPA)	740.0	Bladder	53	4.8	160
Heart perfusion (Tl-201 chloride)	111.0	Kidney	33	10.4	347
Tumor (Ga-67 citrate)	111.0	Colon	21	12.2	407

NOTE: MBq = megabecquerel; mGy = milligray; EDE = effective dose equivalent; mSv = millisievert; DTPA = diethylenetriamine pentaacetic acid (pentetate).
SOURCES: Mettler et al., 1986; NCRP, 1989.

The annual procedure rate per 1,000 population was 16, 33, and 33 examinations in 1972, 1982, and 1993, respectively. After a period of rapid expansion in the 1970s, nuclear medicine utilization has grown only as fast as the population. The impact of CT and MRI accounts for the decrease in brain procedures as well as for the slower growth rate (compared with the 1970s) of a number of procedures related to other parts of the body.

Radiation Doses

Patient-specific radiation dose. Radiation dose from nuclear medicine procedures depends on the radiopharmaceutical, the administered activity, and individual patient metabolism. Because the radiopharmaceutical is taken up in a nonuniform manner, the organ dose varies dramatically. To aid in clinical applications, radiopharmaceutical manufacturers provide dosimetry estimates based on standardized adult and child metabolic and anatomic models. For each procedure, the activity for a typical dose is calculated for individual organs and for the whole body. In combination with organ weighting factors, EDEs can also be calculated. Table 2.8 shows administered activity, absorbed dose of the maximally exposed organ, EDE, and fraction of EDE relative to normal background for several common nuclear medicine procedures.

With the exception of the I-131 sodium iodine thyroid scan, the EDE per procedure varies from one-tenth to several times the 3 mSv of natural background radiation. The I-131 sodium iodine gives an extremely high thyroid dose (almost 2,000 times background), because beta particles (electrons) emitted during radioactive decay are absorbed locally in thyroid tissue. Nuclear medicine procedures generally result in slightly higher patient exposure compared with diagnostic x-ray procedures. The reasons for this include the higher doses necessary for image clarity, the exposure time required for observing certain biological functions, and the fact that the radioactive material is not immediately flushed from the system, but continues to decay in the patient's body after the procedure is complete.

Collective dose. The NCRP has estimated collective dose to the U.S. population from diagnostic nuclear medicine procedures using the same approach discussed earlier for diagnostic radiology (average EDE per procedure times total number of procedures). For 1982, the NCRP produced an estimate of 32,100 person-Sv, with a per-person EDE of 0.14 mSv (Edwards, 1995).

The relevance of these figures is that, compared with medical x-rays, diagnostic nuclear medicine contributes a lower collective dose and a lower per-person dose. The reason is that the total number of nuclear medicine procedures is much lower than that of medical x-ray procedures. Age-weighted collective dose (which takes into account the older age of the patient population) was

TABLE 2.9 Selected Reactor-Produced Radionuclides and Their Biomedical Applications

Radionuclides	Use
Arsenic-77	In cancer therapy
Bromine-82	In metabolic studies and studies of estrogen receptor content
Calcium-47	In studies of cell function and bone formation of mammals and to produce scandium-47
Californium-252	In brachytherapy for treatment of cervical cancer and potentially for treatment of gliomas
Carbon-14	For medical research to trace metabolism of new drugs and other organic carbon-containing molecules
Cerium-141	For research and development on lung densities
Cesium-137	To treat cancer; to measure correct patient dosages of radiopharmaceuticals
Chromium-51	To assess red blood cell survival studies
Cobalt-58	To diagnose pernicious anemia
Cobalt-60	To treat cancer and sterilize surgical instruments
Copper-64	As a clinical diagnostic agent for cancer and metabolic disorders
Copper-67	In cancer therapy and to label antibodies for cancer therapy
Dysprosium-165	To treat rheumatoid arthritis
Dysprosium-166	Decays to holmium-166, which is used in cancer therapy
Einsteinium-253	To radiolabel antibodies for cancer therapy
Erbium-169	To treat rheumatoid arthritis
Fermium-255	To radiolabel antibodies for cancer therapy
Gadolinium-159	In cancer therapy
Gold-198	In cancer therapy and to treat rheumatoid arthritis
Holmium-166	In cancer therapy and to treat rheumatoid arthritis
Iodine-125	As a potential cancer therapeutic agent and for basic biomedical research
Iodine-129	To check radioactivity counters in in vitro diagnostic testing
Iodine-131	To diagnose and treat thyroid disorders including cancer and for basic biomedical research
Iridium-191	To assess cardiac function especially in the pediatric population
Iridium-192	In cancer therapy
Lutetium-177m	In cancer therapy and to label antibodies for cancer therapy
Molybdenum-99	To produce technetium-99m, the most commonly used radioisotope in clinical nuclear medicine
Osmium-191	Decays to iridium-191m, which is used for cardiac studies

Osmium-194	Decays to iridium-194, which is used in cancer therapy
Palladium-103	In the treatment of prostate cancer
Phosphorus-32	In cancer treatment, cell metabolism and kinetics, molecular biology, genetics research, biochemistry, microbiology, enzymology, and as a starter to make many basic chemicals and research products
Phosphorus-33	In cancer treatment, molecular biology and genetic research, and biochemical and enzymological studies
Platinum-195m	In pharmacokinetic studies of antitumor agents
Rhenium-186	As a bone cancer therapeutic agent and to radiolabel various molecules as cancer therapeutic agents; also used to treat rheumatoid arthritis
Rhenium-188	For treatment of medullary thyroid carcinoma and alleviation of pain in bone metastases
Samarium-145	For treatment of ocular cancer
Samarium-153	To radiolabel various molecules as cancer therapeutic agents and to alleviate bone cancer pain
Scandium-47	In the therapy of cancer
Selenium-75	In protein studies in life science research
Silver-111	In cancer therapy
Strontium-85	To study bone formation and metabolism
Strontium-89	To alleviate metastatic bone pain
Strontium-90	Decays to yttrium
Sulfur-35	In studies of cell metabolism and kinetics, molecular biology, genetics research, biochemistry, microbiology, enzymology, and as a starter to make many basic chemicals and research products
Technetium-99m	The most widely used radiopharmaceutical in nuclear medicine imaging
Tellurium-123m	For research and development on lung densities and calibrating; also used in cardiology
Tin	117m For palliative treatment of bone cancer pain
Tritium (hydrogen-3)	To make tritiated water, which is used as a starter for thousands of different research products and basic chemicals, and for life science and drug metabolism studies to ensure the safety of potential new drugs
Tungsten-188	Decays to rhenium
Xenon-133	In nuclear medicine for lung ventilation and perfusion studies
Yttrium-90	To radiolabel various molecules as cancer therapeutic agents

SOURCE: Adelstein and Manning, 1995, Table 3.1, pages 38-39; reprinted with permission.

TABLE 2.10 Selected Accelerator-Produced Radionuclides and Their Biomedical Applications

Radionuclide	Uses
Arsenic-74	A positron-emitting chemical analogue of phosphorus
Barium-128	Parent in generator system for producing the positron-emitting cesium-128, a potassium analogue
Beryllium-7	Berylliosis studies
Bismuth-205	Bismuth biological distribution
Bismuth-206	Bismuth biological distribution
Bromine-77	Radioimmunotherapy
Bromine-80m	Radioimmunotherapy
Cadmium-109	To analyze metal alloys for checking stock, scrap sorting
Cerium-139	Gamma-ray calibration source
Cobalt-57	Calibration of imaging instruments
Copper-61	Positron emitter for studies requiring longer time periods
Copper-64	Positron emitter for studies requiring longer time periods; radioimmunotherapy
Copper-67	Radioimmunotherapy
Germanium-68	Parent in the generator system for producing the positronemitting gallium-68; required in calibrating PET tomographs, potential antibody label
Indium-111	Radioimmunotherapy
Iodine-123	SPECT brain-imaging agent
Iodine-124	Radioimmunotherapy; positron emitter
Iron-52	Iron tracer, positron emitter
Iron-55	X-ray fluorescence source
Magnesium-28	Magnesium tracer
Mercury-195m	Parent in the generator system for producing gold-195m which is used in cardiac blood pool studies
Ruthenium-97	Hepatobiliary function; tumor and inflammation localization
Scandium-47	Radioimmunotherapy
Strontium-82	Parent in generator system for producing the positron-emitting rubidium-82, a potassium analogue
Tantalum-179	X-ray fluorescence source (substitute for the alpha-emitter gold-241 which is used in cardiac studies)
Thallium-201	Cardiac imaging agent
Tungsten-178	Parent in generator system for producing tantalum-178, short-lived scanning agent
Vanadium-48	Nutrition and environmental studies
Xenon-122	Parent in generator system for producing the positron-emitting iodine-122
Xenon-127	Used in lung ventilation studies
Yttrium-88	Radioimmunotherapy

Zinc-62	Parent in the generator system for producing the positron-emitting copper-62
Zirconium-89	Radioimmunotherapy, positron emitter

NOTE: PET = positron emission tomography; SPECT = single photon emission tomography.
SOURCE: Adelstein and Manning (1995), *Isotopes for Medicine and the Life Sciences,* Table 4.1, page 59; reprinted with permission. Copyright 1995 by the National Academy of Sciences.

13,500 person-Sv in 1982. Because nuclear medicine is not expanding faster than the population, collective dose for 1993 should scale to the U.S. population in that year. This would result in a collective dose of 35,400 person-Sv and a per-person dose still at 0.14 mSv.

Radiation Regulation and Control

Radiation regulation and control of medical nuclides and radiation safety in nuclear medicine are historically rooted in federal statutes. Many of the radionuclides used in nuclear medicine are produced using a nuclear reactor. Reactor development grew out of the World War II Manhattan Project, and all reactor related issues were regulated by the federal government through the Atomic Energy Commission until 1974. When the Atomic Energy Commission was split in that year into the NRC and the Energy Research and Development Agency (now the Department of Energy), regulation of the medical use of reactor-produced radionuclides was given to the NRC.

The NRC does not regulate all aspects of medical radionuclides, however. Accelerator-produced radionuclides, such as T1-201, Ga-67, and indium-111 (In-111), are controlled by state regulation. Table 2.9 lists byproduct radionuclides that fall within NRC regulatory authority, and Table 2.10 lists accelerator-produced radionuclides that are regulated, if at all, by the states.

As noted in Chapter 3, regulation in this area is widely dispersed across agencies in the federal government. For example, shipping and receiving of radionuclides are regulated by the Department of Transportation. Disposal of non-reactor-produced radionuclides is regulated by the Environmental Protection Agency.

A further complication is that states may agree to regulate reactor-produced nuclides on their own. Such Agreement States (see Chapter 3) must have state regulations that meet or exceed federal regulations. Twenty-nine states, including most of the heavily populated states, are Agreement States. Hence most nuclear medicine procedures are performed in Agreement States, under the direction of state regulations.

Because state regulations cannot be weaker than federal regulations, the regulation of nuclear medicine is essentially determined by 10 CFR Parts 20 and 35. Part 20 sets forth general radiation protection standards and regulations; Part

35 covers medical uses of radionuclides. Regulation is achieved through licensing of institutions and "authorized users."

To receive, possess, or administer medical radionuclides, an institution must be issued a license that commits the institution to observe NRC rules and regulations, as set forth in the CFR and expanded on in "Regulatory Guides." Typically, a hospital must have a radiation safety committee, a radiation safety officer, a high-level administrative commitment to the provisions of the radiation safety program, written policies and procedures for radiation safety and isotope utilization that are substantially identical to NRC model guidelines, and sufficient resources and manpower to carry out the program.

To receive and administer radionuclides, a physician must be named on the license as an authorized user. This requires either specialty board certification or completion of several hundred hours of prescribed course work in addition to a medical degree. The regulations do not prohibit a physician who is not an authorized user from interpreting nuclear medicine images.

In response to concerns about "misadministrations," which are defined as incidents in which the wrong nuclide or a wrong amount of the nuclide was administered to a patient, the NRC now requires hospitals to institute a "quality management" (QM) program (see Chapter 3). Although this program applies primarily to therapeutic radionuclides, any diagnostic study involving more that 30 microcuries of I-131 sodium iodine (see Table 2.10) must follow special policies and procedures. For instance, there must be a "written directive" signed by an authorized user prior to administration, the activity must be independently checked, and the patient must be identified by two independent means. Records of nuclide administrations must be reviewed quarterly and the entire program annually. Whether such programs will have an impact on the misadministration rate remains to be seen.

THERAPEUTIC APPLICATIONS OF IONIZING RADIATION

Ionizing radiation applied for therapeutic (as contrasted with diagnostic) purposes is also typically classified into categories based on whether the source of the radiation is external or internal to the patient. Respectively, these areas are called radiation oncology and teletherapy (external sources), brachytherapy (internal), and therapeutic nuclear medicine (internal). Each of these areas is discussed below.

External Sources: Radiation Oncology and Teletherapy

General Approaches

Radiation oncology is the specialty of medicine that deals with treating cancer patients with ionizing radiation. It employs teletherapy, which is radiation

therapy delivered by an external beam of radiation, as described below. Radiation therapy is also used to treat noncancerous conditions on a selective basis.

At the present time, at least 50 to 60 percent of all cancer patients receive radiation therapy sometime during the course of their illness. The intent of this treatment is to deliver a dose of radiation that destroys tumor cells while limiting the dose of radiation to normal cells. In a typical course of treatment, radiation is delivered five days per week in fractions of the total dose. Depending on the tumor type, stage of disease, and proximity of organs or tissues to which only a limited dose is allowed, the total tumor dose may range from 30 to 70 gray (Gy).

Patients receive radiation therapy for either curative or palliative reasons. Curative treatment is possible for any tumor that has not metastasized (spread beyond the primary tumor to distant locations). Cure is more likely for primary tumors that are small and that respond more readily to radiation than the surrounding healthy normal tissue. In early breast cancer, for instance, an appropriate dose schedule effectively kills residual tumor cells remaining in the breast following surgery with no long-term damage to normal breast tissue. In less favorable circumstances involving localized but radioresistant tumors, such as glioblastoma (a type of brain tumor), patients are given a dose sufficient to shrink the tumor without significantly harming the more radiosensitive normal brain tissue that surrounds the lesion.

Even if metastatic spread of a tumor precludes curative treatment, palliative radiation therapy is often beneficial and improves the quality of the patient's remaining life. Radiation is indicated to alleviate pain from metastases to bone, to control bleeding or obstruction caused by tumor growth, and to control neurological symptoms due to brain or spinal metastases.

As stated above, teletherapy is radiation therapy delivered using an external beam of ionizing radiation. Options include gamma rays (from a radioactive cobalt-60 (Co-60) source) and photons or electrons (from an x-ray generator or accelerator). Linear accelerators and other electron accelerators produce high-energy photon and electron beams for treating patients with cancer. A typical treatment uses two or more photon beams aimed from various angles that intersect at the tumor. Electrons, which have less power to penetrate tissue, are used to treat skin lesions, superficial lymph nodes, and other tumors situated near the surface of the patient.

In addition to "conventional" radiation therapy, experts in radiation oncology have developed several other methods of external beam therapy. *Intraoperative radiation therapy* (IORT) uses electrons to treat tumors that have been surgically exposed. IORT delivers a single high dose of radiation directly to the tumor after overlying and surrounding tissue have been temporarily moved out the way. IORT is of greatest use for accessible tumors of the abdomen and pelvis that cannot be removed surgically. *Stereotactic radiosurgery* (SRS) delivers radiation beams to a small target within the skull. The resulting dose distribution yields a small region of high dose precisely conforming to the target. SRS has

been proven to be an effective treatment for arteriovenous malformations, and it is being evaluated for treatment of primary and metastatic brain tumors. *Dynamic conformal radiation therapy* uses a computer to shape the radiation field continuously as the linear accelerator rotates about a patient. In combination with three-dimensional treatment planning, this technology facilitates the treatment of tumors with complex geometric shapes and allows radiation therapy clinicians to increase tumor dose and simultaneously reduce normal tissue dose.

Clinical Uses in Illustrative Medical Conditions

Cancer can be treated in three principal ways: surgery, radiation therapy, and chemotherapy. Surgery and radiation therapy are localized treatments, whereas chemotherapy provides systemic treatment for both local and disseminated disease. The choice of treatment depends upon which modality or combination of modalities offers the patient the greatest chance of cure, the best preservation of normal function and appearance, and the least chance of harmful side effects. Radiation therapy alone, or combined with conservative surgery, generally affords the cancer patient the greatest opportunity for curative treatment with functional preservation. This combination is widely employed for a variety of human neoplasms. Breast cancer and prostate cancer illustrate the points.

Breast cancer. Detection and treatment of early breast cancer is a significant health care issue for the United States. With the advent of effective breast cancer screening programs, more breast cancers are being detected at an earlier stage. The American Cancer Society estimates that about 183,000 new cases of breast cancer will be diagnosed in 1995 (Steele et al., 1994). The functional and cosmetic results of treatment are of significant concern to patients with early breast cancer. Clinical trials have established that breast-conserving treatment, consisting of local tumor excision and radiation therapy, results in a 10-year survival rate equal to that of radical surgery (masectomy). Following limited surgical excision of the tumor (lumpectomy), all remaining breast tissue is treated with radiation to a uniform dose of 45 to 50 Gy. The surgical site is then "boosted" with an additional 10 to 20 Gy delivered with either electrons or an interstitial radioactive seed implant (see discussion of brachytherapy, below). As more clinicians have become aware of these results, in part through the publication of national consensus panel recommendations, the proportion of breast cancer patients treated with this approach has increased. For more advanced breast cancer, radiation therapy also is used to irradiate the chest wall after mastectomy to reduce the rate of local recurrence.

Prostate cancer. Radiation therapy also plays a major role in the treatment of prostate cancer. Screening programs, particularly prostate specific antigen testing, have resulted in a dramatic increase in the number of new cases diagnosed each year. Early-stage prostate cancer can be successfully treated with

surgery (prostatectomy), external beam radiation therapy, or radioactive seed implant. Both radiation therapy and modern nerve-sparing prostatectomy maintain potency in 50 to 70 percent of patients. A typical treatment is delivered using four or more radiation beams, intersecting at the prostate. Customized shielding blocks are used to protect nearby uninvolved anatomical structures, such as the posterior wall of the rectum. Depending on the stage of the disease, a total dose of 60 to 72 Gy is delivered at a rate of 1.8 or 2 Gy per day, five days per week, over a period of six to eight weeks. Seven-year survival rates for patients with prostate cancer that has not spread extensively range from 70 to 80 percent for moderately advanced disease to greater than 90 percent for early-stage disease.

Palliative concerns. Radiation therapy also provides effective palliative treatment for patients with various types of cancers. Dose and fractionation schedules are variable, but the typical course of therapy is 30 Gy given in 10 fractions over a two-week period. Approximately 90 percent of patients receive some relief from the pain of bone metastases, and 54 percent receive complete relief. Hemi-body or whole-body photon irradiation is occasionally performed for widespread metastasis of cancer to the skeleton. Widely disseminated bone metastases can also be treated with systemic radionuclides (discussed in connection with therapeutic nuclear medicine, below).

Brain metastases most frequently are treated by irradiating the entire cranial contents, although solitary lesions may be treated with a much higher effective dose by stereotactic radiosurgery. About 80 percent of patients obtain relief of neurological symptoms, and 50 percent remain free from recurrence of brain metastases until the time of death.

Utilization Rates

Number of treatments by site. Use of radiation therapy in cancer is a major element of health care today. The distribution of radiation therapy treatments by site in the body roughly follows the distribution of cancer incidence, although there are several types of malignancy that are rarely treated using radiation. Shown in Table 2.11 is the estimated number of new cases of cancer by site for 1995, together with a rough approximation of the number of those cases that may receive radiation therapy. In addition, by giving the percentage represented by each site of the total number of new cases treated with radiation, Table 2.11 shows which cancer sites are more commonly treated with radiation.

Overall, approximately 1.3 million new cases of cancer will be identified this year; of these, about 41 percent will receive radiation treatment. In addition to these new cases, previously diagnosed patients who return for relief of the pain or other problems of metastatic disease or for recurrent disease are also

TABLE 2.11 Estimated Number of New Cancer Cases by Site in 1995

Site	No. of New Cases	No. Treated with Radiation[a]	% of Total Treated with Radiation
Oral cavity			
Lip	2,550	800	0.2
Tongue	5,550	1,700	0.3
Mouth	11,000	3,300	0.6
Pharynx	9,100	2,700	0.5
Digestive organs			
Esophagus	12,100	6,000	1.2
Stomach	22,800	0	0
Small intestine	4,600	0	0
Large intestine	100,000	10,000	1.9
Rectum	38,200	19,100	3.7
Liver and biliary	18,500	900	0.2
Pancreas	24,000	19,200	3.7
Other digestive	2,800	300	0.1
Respiratory system			
Larynx	11,600	4,000	0.8
Lung	169,900	136,000	26.4
Other respiratory	4,800	2,400	0.5
Bone	2,070	200	<0.1
Connective tissue	6,000	1,800	0.4
Melanoma of skin	34,100	3,400	0.7
Breast	183,400	128,400	24.9
Genital organs			
Cervix uteri	15,800	4,700	0.9
Corpus uteri	32,800	24,600	4.8
Ovary	26,600	2,700	0.5
Other, female	5,700	2,900	0.6
Prostate	244,000	73,200	14.2
Testis	7,100	2,100	0.4
Other, male	1,100	300	0.1
Urinary organs	79,300	11,900	2.3
Eye	1,870	200	<0.1
Brain or central nervous system	17,200	14,600	2.8
Endocrine glands	15,380	1,500	0.3
Leukemia	25,700	300	0.1
Other blood or lymph			
Hodgkin's disease	7,800	3,900	0.8

Non-Hodgkin's lymphoma	50,900	17,800	3.5
Multiple myeloma	12,500	4,500	1.9
All other and unspecified	45,230	4,500	0.9
Total	1,252,050	509,900	100.0

[a] Data are rough estimates of how many new cases may receive radiation therapy. Although the number of estimated new cases is fairly reliable, the distribution of therapy cases is more difficult to predict, owing to its dependence on practice patterns.
SOURCE: American Cancer Society (see Wingo et al., 1995).

treated with radiation therapies. The actual frequency distribution by site is quite variable, because it depends on local patterns of care, the initiation of new treatment protocols, and the retirement of old ones.

Patterns of Care Studies. The ACR, through the Patterns of Care Studies (POCS), has conducted periodic surveys of the status of radiation oncology in the United States. The relatively small number of centers and physicians involved in the specialty of radiation oncology (and the field's exclusive focus on cancer) facilitate in-depth surveys of the patterns of care in clinical radiation therapy. The POCS measure the size and composition of the radiation oncology care delivery system in the United States and document both the process of care and patient outcomes. Over time, the POCS also contribute information leading to changes in process and improvements in outcomes.

The POCS data are valuable in placing radiation oncology in perspective among the cancer treatment modalities. Based as they are on statistically valid samples of the total spectrum of practice in the United States, the numbers can be relied upon to demonstrate what is experienced in the community in terms of tumor response, survival, and complications. Some of these outcomes data are presented later in this section.

Table 2.12 summarizes the results of those surveys that tracked facilities and work load, showing data for selected years between 1975 and 1990. Between 1975 and 1990, for example, the total number of facilities increased by just under 300 while treatment machines rose by more than 1,000. In the same period, the number of new patients rose by nearly 180,000 persons (or about 12,000 a year on average).

Much of the growth in machines and new patients in this period occurred between 1986 and 1990, and most of this can be attributed to the expansion of freestanding (nonhospital-based) radiation oncology centers. In 1986, approximately 20 percent of facilities were freestanding, whereas just four years later the figure had increased to 27 percent.

TABLE 2.12 Number of Radiation Oncology Facilities, Number of Treatment Machines, and Patient Loads, 1975-1990

	1975	1980	1986	1990
Facilities	1,047	1,083	1,144	1,321
Treatment machines				
Linear accelerator/betatron	407	801	1,294	1,893
Cobalt	970	825	671	504
Total	1,377	1,626	1,965	2,397
New patients	312,548	377,837	444,558	492,120
Per 1,000 population	1.49	1.67	1.85	1.98
Per facility	299	349	389	373
Per machine	227	233	226	205

SOURCE: ACR Patterns of Care Study, Owen et al., 1992.

The POCS data reported here reflect the level of clinical activity for new patients only. If an average of 20 to 25 treatments per patient is assumed, in 1990 the estimated number of patient-treatments for this group would range between 9.8 million and 12.3 million. Clearly, however, radiation oncology has a considerably greater work load than that. The total number of patients seen per year is the sum of new patients and "old" patients (previous patients returning for additional treatment). Depending on practice patterns, these prior patients may account for 30 to 50 percent of total patient load. By using the same 20-to-25 treatments per patient assumption, in 1990 the total number of patient-treatments could be estimated to range between 12.7 million and 18.4 million.

One influential result of the sequential POCS is the availability of outcomes data based on a properly balanced sample of the total practice in the United States. These data show overall survival, disease-free survival, recurrence rates, and complications. Taken as a whole, the data illustrate remarkably high survival rates and comfortably low complication rates. Rates, of course, strongly relate to variables such as tumor type, disease stage, and patient age.

Advances in radiation oncology continue to improve a patient's opportunity for long-term survival. For stage I and II cancers of the tongue and floor of the mouth, recurrence rates at the original cancer site have been reduced from 41 percent (when treated with external beam alone) to 26 percent (when treated with interstitial brachytherapy). For women with carcinoma of the cervix, the four-year survival rate increased from 62 to 73 percent; 15 years after the 1973 study, 51 percent of patients with stage I carcinomas are still alive. Not only survival is at issue; radiation therapy of prostate cancer maintains potency in patients at the same rate as state-of-the-art nerve-sparing prostatectomy.

The POCS have also increased knowledge of dose effectiveness. Stage B prostate cancer shows greatest sensitivity to doses between 60 and 70 Gy, with no advantage seen in higher doses. The higher risks associated with doses over 70 Gy, however, may be acceptable to patients with stage C prostate cancer.

Collective Dose

Few recent estimates of collective dose to the U.S. population from radiation therapy have been performed. Although such a calculation could be done, it would be of questionable validity and usefulness, for several reasons. Organ weighting factors used to define EDEs are derived for healthy populations exposed to comparatively low (less than a few grays) radiation levels; they do not take into account the effects of fractionated high-level exposure or implications of a population of cancer patients. Thus, collective dose from radiation therapy should not be used to estimate rates of radiation-induced cancer among the patient population that already has cancer.

The incidence of secondary neoplasms following radiation therapy has been extensively reported in the literature. Various types of radiation-induced cancer have been observed to arise both in the treatment area and at distant sites that were irradiated by scattered and leaking radiation. The issue of secondary tumors can be significant in treatment decisions for patients with curable tumors and otherwise long life expectancies. For instance, elevated incidence of in-field sarcoma has been observed 10 years following radiotherapy for breast cancer. Elevated rates of cancer have also been observed in children receiving cranial irradiation for leukemia and in young adults treated for Hodgkin's disease and seminoma. Of course, some chemotherapeutic agents also increase the risk of later malignancy, so choices among therapeutic options are often difficult.

Radiation Regulation and Control

Regulation and control of external beam radiation therapy is analogous to that of diagnostic radiology and nuclear medicine. In NRC states, the federal government regulates cobalt teletherapy (because Co-60 is reactor produced), and the state regulates all other external beam therapy. In Agreement States, the state regulates all external beam therapy.

Typical state laws specify radiation shielding design levels for facility construction, required interlocks, area radiation monitors, warning labels, and access control. Some states may specify qualifications, training, and licensure of equipment operators and (rarely) radiological physicists, as well as content and frequency of accelerator calibrations. The level of oversight varies considerably from state to state, with some states providing inspection by state radiologic health personnel and others simply registering the existence of the facility.

The regulation of cobalt teletherapy is unique: 10 CFR Part 35 sets out detailed requirements for obtaining a license to possess and operate a cobalt teletherapy unit. Because the regulations of Agreement States must comply with NRC regulations, Part 35 essentially regulates all cobalt teletherapy treatments in the United States. The NRC requires that physicians who are authorized users of Co-60 teletherapy machines be board certified or meet several hundred hours of training requirements. A "teletherapy physicist" must be named on the license and meet similar qualifications. Personnel operating the unit must receive annual instruction in radiation protection and emergency procedures.

The QM section of Part 35.32 defines the required components of a valid physician prescription. It also requires a system of double checks for dosimetry calculations; documented institutional validation of computerized treatment planning software; and identification, prior to each treatment, of the patient by two independent methods. If it is discovered that a patient's delivered total dose varies by more than 20 percent (greater or less) from the prescribed dose, the NRC Operations Center in Washington, D.C., must be notified within one calendar day of discovery of the "misadministration" and the event is thoroughly investigated. In addition, the patient and the patient's referring physician must be notified within 24 hours. All NRC-required records, such as dosimetry equipment calibrations, annual and monthly teletherapy calibrations, personnel training, documentation of required checks in patient charts, and investigations of misadministrations, must be available for unannounced on-site NRC inspection.

The FDA regulates equipment design and construction. Because linear accelerators and radiation therapy treatment planning systems are Class III medical devices, their safety and manufacture is controlled by the FDA. Problems with the operation of such equipment, particularly those resulting in an adverse patient outcome, must be reported subject to the Safe Medical Device Act, as amended in 1991.

Internal Sources: Brachytherapy

Overview

Malignant neoplasms also may be treated by radiation sources placed within the body. Brachytherapy is the placement of sealed sources of radionuclides (called seeds) either in body cavities (intracavitary brachytherapy) or directly into body tissues (interstitial brachytherapy). Chief among the advantages of brachytherapy compared to other methods is that the highest radiation dose is delivered where it is most needed. Historically, brachytherapy developed before teletherapy, well before optimal sources of external beam radiation were available.

TABLE 2.13 Some Properties of Radionuclides Commonly Used for Brachytherapy

Element	Isotope	Half-Life	Source Forms	Implant Type
Gold	Au-198	2.7 days	Seeds	Permanent
Palladium	Pd-103	17 days	Seeds	Permanent
Iodine	I-125	60 days	Seeds	Permanent
Iridium	Ir-192	74 days	Seeds, wire	Temporary
Cesium	Cs-137	30 years	Tubes, needles	Temporary
Strontium	Sr-90	29 years	Plaque	Temporary

NOTE: Radionuclides are listed in approximate order of prevalence of use.

The original method of brachytherapy is now sometimes called "low dose rate" (LDR) brachytherapy. The radioactivity of sources available at the time of brachytherapy's development was such that, to give a tumor-killing dose, sources had to be left in place for days. Because of the low activity, these sources could be handled manually. LDR therapy typically involves tumor dose rates of from 0.3 to 0.6 Gy per hour.

In the past 20 years, techniques have been developed to manufacture high-activity sources that provide dose rates of 1 to 2 Gy per minute. With "high dose rate" (HDR) brachytherapy, a treatment can be completed in a matter of minutes. The high activity of these sources precludes their manual handling. To handle these HDR sources, intracavitary brachytherapy employs applicators (metal or plastic devices inserted into a body cavity) into which the sealed radioactive sources are later inserted, or "afterloaded," by a computerized robotic device. This approach avoids having radioactive sources in the operating room while others are present.

For interstitial brachytherapy, sources are either inserted directly into tissues or are afterloaded into hollow needles or plastic catheters that pierce the tumor. In some cases, seeds are implanted directly into tissues and left permanently. For radiation safety and radiobiological considerations, permanent implants are feasible only with nuclides having a fairly short half-life.

In the early days of brachytherapy, radium-226 (Ra-226) was the only radionuclide available. After World War II, reactor-produced nuclides became available and the use of Ra-226 gradually declined. The radionuclides commonly applied in brachytherapy in the United States today are listed in Table 2.13 in approximate order of prevalence of use.

Cesium-137 (Cs-137) is used almost exclusively for LDR intracavitary brachytherapy. Iridium-192 (Ir-192) is used both for LDR interstitial implants and as a single high-strength source for HDR treatments. Iodine-125 (I-125) seeds have been used extensively for permanent interstitial implants at a wide variety of sites, particularly the prostate. Recently, palladium-103 (Pd-103) has been developed for use in permanent implants, because its shorter half-life delivers

the total tumor dose over a shorter period of time. Gold-198 (Au-198) seeds also are used for permanent implants requiring rapid delivery of the total dose. Strontium-90 (Sr-90) plaques are used to irradiate very superficial lesions, and use of a strontium applicator is confined almost entirely to the treatment of pterygium, a proliferative disorder of the eye.

Types of Procedures

Brachytherapy is used alone or in conjunction with external beam radiation therapy to treat a wide variety of malignant neoplasms. Perhaps the most prevalent is the use of LDR and HDR intracavitary brachytherapy for treatment of gynecological malignancies. It is most often used as a local boost following wide-field pelvic teletherapy. The brachytherapy boost is delivered in one or more fractions, each of which requires insertion of applicators into the uterus and vagina. Depending on the overall boost dose and the number of fractions, each implant may deliver from 6 to 20 Gy. LDR treatments last a few days, whereas HDR treatments last a few minutes. Because of the high dose rate, the consequences of a mispositioned or lost source are much more severe for HDR treatments.

Selected prostate cancers can be treated by a permanent interstitial implant. This technique involves implantation of 50 or more I-125 or Pd-103 seeds into the prostate. Because the procedure is done by transperineal needle insertion under ultrasonic visualization, open pelvic surgery is not required. A tumor dose of from 100 to 200 Gy (depending on the size of the gland and the activity implanted) is delivered as the radionuclide totally decays. Early clinical results in well-selected cases are similar to external beam radiation therapy and prostatectomy.

Iridium-192 seeds, spaced 1 centimeter apart inside nylon ribbons that can be after loaded into nylon catheters, are used to treat many sites. For example, interstitial implantation in the breast may be used to provide a localized boost dose in breast-conserving therapy. A single catheter, inserted into a partially obstructed bronchus, esophagus, or bile duct, may be used to relieve obstruction. Boost treatment of primary head and neck cancers, particularly of the tongue and floor of the mouth, may be accomplished by iridium seed implantation. A typical treatment involves surgical placement of 5 to 10 catheters inserted through the tumor. Each catheter is loaded with a length of ribbon to provide an appropriate number of seeds for the size of the tumor in the plane of the catheter. A boost dose of 10 to 20 Gy is then delivered in one to two days.

Radiation Regulation and Control

Radiation regulation and control of nuclides used for brachytherapy is similar to that for diagnostic nuclear medicine. Because a majority of nuclides are

reactor produced, the regulatory environment is primarily determined by the NRC, with Agreement States following suit. However, accelerator-produced nuclides are regulated by state law. The Department of Transportation sets packaging and labeling requirements for transport of therapeutic radionuclides.

The QM requirements of 10 CFR Part 35, as discussed above with regard to cobalt teletherapy, apply also to brachytherapy (and to therapeutic unsealed radionuclides, discussed below). No treatment may be delivered without a written directive from a physician named on the authorized user list of the facility license; the patient's identity must be confirmed by two independent means before administration; each administration must be carried out in accordance with the directive; and any unintended deviation (misadministration) from the written directive should be identified and reported to the NRC and to the patient, and corrective action should be taken.

The equipment and procedures for HDR remote after loading brachytherapy have been the subject of much regulatory interest. Several incidents of inadvertent patient overdose have been documented, one contributing to the death of a patient, as described in Chapter 1. The NRC recently has published a 60-page collection of current regulations, standards, and guidelines that apply to remote after loading brachytherapy (NRC, 1994). This document integrates statutory requirements of the NRC and FDA with standards and recommendations from international and national organizations such as the ACR, NCRP, American Association of Physicists in Medicine, American National Standards Institute, International Atomic Energy Agency, and National Institute of Standards and Technology.

Internal Unsealed Sources: Therapeutic Nuclear Medicine

Overview

In contrast to the smaller amount of radioactivity utilized in diagnostic nuclear medicine, larger amounts of radioactivity are intentionally chosen for use in therapeutic nuclear medicine. Therapy in nuclear medicine involves oral, intravenous, or intracavitary delivery of radionuclides in liquid form (sometimes called "unsealed" radionuclides). The radionuclide is chosen with the aim of ensuring that subsequent physiological redistribution will concentrate the radioactivity in the target tissue and, at the same time, reduce the radioactivity in surrounding normal tissues. Radionuclides suitable for use in therapeutic nuclear medicine must either localize in their elemental form (such as iodine uptake in the thyroid gland) or be bound to an appropriate pharmaceutical or antibody. A list of common nuclides used for therapeutic nuclear medicine is shown in Table 2.14.

TABLE 2.14 Radionuclides Commonly Used for Therapeutic Nuclear Medicine

Element	Isotope	Half-Life (days)	Chemical/Biological Form
Gold	Au-198	2.7	Colloid
Iodine	I-131	8.0	Sodium iodine, meta-iodobenzylguanidine, monoclonal antibodies
Phosphorus	P-32	14.3	Phosphate, colloid
Strontium	Sr-89	52.7	Strontium chloride

Following therapeutic nuclear medicine interventions, some radiopharmaceuticals cause the patient's urine, sweat, saliva, and blood to contain a high level of radioactivity. In many instances, patients must be hospitalized for several days to prevent contamination of the public.

Types of Procedures and Number of Treatments

Iodine-131 (I-131) is the most commonly used therapeutic radiopharmaceutical, especially for treatment of hyperthyroidism and primary and metastatic thyroid cancer. The NRC has estimated annual use of I-131 for thyroid ablation at 50,000 administrations per year and for thyroid cancer at 10,000 administrations per year.

Intravenously administered radioiodine in the form of meta-iodobenzylguanidine is used to treat neuroblastoma metastases. Monoclonal antibodies frequently are labeled with I-131 for use in radioimmunotherapy. Recent clinical trials of this modality have shown greatest promise for treatment of neoplasms of the circulatory system, particularly B-cell lymphoma. Radioimmunotherapy of solid tumors is more problematic, both in terms of getting sufficient dose to the tumor and in accurately calculating tumor dose.

Other nuclides are less frequently used to treat a wide range of conditions. Intravenous phosphorus-32 (P-32) is effective in the treatment of myeloproliferative disease, particularly polycythemia vera. Pain from cancer metastases to the bone can be eased with intravenous strontium-89 (Sr-89) chloride. Intracavitary therapy employs P-32 or Au-198 colloid to suppress malignant effusions and dysprosium-165 (Dy-165) macroaggregates for radiation synoviorthesis in rheumatoid arthritis. In all of these applications, patient management is closely coordinated to benefit appropriately from the contributions of surgical, medical, radiation, and nuclear medical specialists.

Radiation Regulation and Control

The same regulatory apparatus that applies to radiation used in brachytherapy applies to radiation used for therapeutic nuclear medicine. For the latter, regulations address the fact that with unsealed source administration, the patient becomes a source of radiation and radioactive contamination. Regulations allow patient excreta to be exempt from treatment as radioactive waste. Hence, disposal of I-131-contaminated urine down the sanitary sewer system is allowed. Contaminated hospital items, such as eating utensils and sheets, must be decontaminated, usually by decay in storage, or disposed of as low-level radioactive waste. The patient may not be released until either the activity remaining in the patient falls below defined limits or the exposure rate 1 meter from the patient dips below 0.05 mSv/hr. Personnel working with large quantities of I-131 sodium chloride are closely monitored for exposure and thyroid uptake.

CHAPTER SUMMARY

Diagnostic and therapeutic clinical applications of ionizing radiation range from the simplicity of taking a chest x-ray to the complexity of treating a brain tumor. Each of these procedures benefits patients.

Differing clinical applications involve varying risks to patients, but the level of risk has much to do with the process and little to do with the source of radiation. Whether a teletherapy machine contains a radionuclide produced by an NRC-regulated reactor, or by a hospital-owned accelerator, is of small import when calculating risk. Yet, as hinted at in this chapter's radiation regulation and control sections, regulation in the field is split along this less important distinction between sources. Not only is this fractured regulatory system illogical, it is also costly. This is explored in more depth in the next chapter, "Regulation and Radiation Medicine."

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3

Regulation and Radiation Medicine

In describing the clinical applications of ionizing radiation, Chapter 2 discusses some of the forms government regulation takes with respect to particular sources of radiation and procedures for applying it. This chapter gives perspective to that discussion by presenting an overview of the entire regulatory system that applies to ionizing radiation in medicine.

The chapter begins by making important general observations about the goals of regulating medical products. It next describes the development of regulation with respect to different types of ionizing radiation products and details the current roles of the Nuclear Regulatory Commission (NRC), the Food and Drug Administration (FDA), the other federal agencies, and the states. The discussion then moves on to examine the fee and non-fee costs of regulation to the regulated community. This section is followed by a summary of qualitative assessments about regulation that the committee found to be prevalent.

REGULATORY GOALS

All regulation of medical products shares two important goals. The first objective of regulation is to protect the public health and safety by preventing the marketing of unsafe or ineffective products. The second goal of regulation is to promote the availability of safe and effective products that will enhance the public health and safety. Regulation of medical products that emit ionizing radiation is no different than regulation of any other form of therapeutic or diagnostic products in these two respects.

For both radiation products and any other form of drug or device, a patient is deliberately exposed to a potentially toxic ingredient because, in the concerted judgment of the patient and the physician, after weighing the risks and benefits of the therapy or diagnosis and of available alternatives, it is considered the most effective and beneficial procedure for the patient. Risks that would never be tolerated for individuals who are not suffering from disease become acceptable for the ill patient because the potential benefits outweigh the potential risks. For all medical products, needless or excessive exposure is never justified. Having accepted a certain level of risk, patients seek assurance that the drug or device is sufficiently reliable and that the health personnel administering the therapy are sufficiently competent.

Safety is not the only regulatory goal for radiation products or any other form of drug or device. Although the legislation enacted by Congress to regulate radiation products as well as other drugs and devices often focuses primarily upon safety, inherent in all of this legislation is the equally important goal of promoting new medical technology that will address the nation's important health needs. Many of our most serious diseases can effectively be treated in the future only through the development of new medicine, including radiation products, that will make major advances in diagnosis and therapy.

These twin goals for regulation of medical products—promoting safety and promoting technological advance—require a delicate balance. Overprotection against unsafe products will reduce technological advances, raise health care costs, and harm the public health. Overpromotion of technological advances could reduce safety protections and also harm the public health. Inevitably, regulators must balance safety, effectiveness, the need for important new medical products, the cost of complying with regulatory requirements, and access by patients to new therapies on a reasonable timetable.

THE CURRENT REGULATORY FRAMEWORK

How Society Regulates Health Care Delivery

Government regulation of pharmaceutical products, and of the health professionals who administer them, has a long and complex history. At the time our country was founded, there was very little regulation of either products or practitioners. Injured consumers could bring suit in the courts for damages caused by unsafe or ineffective medical products only under limited conditions; and neither licensure nor minimum training was necessary to practice medicine. State regulation of domestic drugs and federal regulation of imported drugs began in the mid-1800s, but premarket testing and approval was not a part of these early programs. The basic philosophy was that consumers should be prudent purchasers, scrutinizing the quality of the goods and services offered in an open market economy.

Beginning with the Biologics Act of 1902 and the Pure Food and Drugs Act of 1906, Congress has enacted increasingly stringent controls over all medical care products throughout this century. As the potential risk of increasingly sophisticated drugs and devices has been recognized, new forms of government control have been imposed.

For all forms of medical products, regulation is justified by the dangers that could be presented by unsafe materials, ineffective products, and incompetent professionals. Many drugs and devices are inherently injurious when applied under any but the strictest regimens. Inappropriate use of drugs or devices can injure or kill a patient. Radiation used in medicine presents the additional concern that it can harm not only the patient, but also the health professional who administers it.

Another justification for government regulation is the fear that patients might have inadequate information, be unable to interpret available information, or make bad decisions even when information is available and understood. This concern persists despite growing patient insistence on personal involvement in making decisions about their own care, particularly when confronted with life-threatening disease. Medical decisions are often viewed as different from other consumer decisions because time is frequently of the essence and emotions arising from emergencies may interfere with rational choice. Regulation is thus intended to facilitate informed and rational decision making and to protect against unwise choices.

Although these factors justify some level of regulation, not all societies and not all individuals agree on the appropriate amount of public protection. The same pharmaceutical product may be available by prescription in some countries and without a prescription in other countries. The degree of government review of drugs and devices prior to marketing varies even among the most sophisticated countries. Countries also have differing standards for licensing health professionals. In all of these areas, the United States has been relatively risk averse and has chosen to impose a high level of regulation. There is overlapping and often contradictory regulation of health care by many agencies at both the federal and state levels. This complex regulatory framework is discussed next.

The Regulatory Framework

Regulatory authority over ionizing radiation in medicine is widely dispersed among several government agencies at the federal, state, and local levels. At the federal level, the NRC and the FDA exercise primary regulatory authority over the use of ionizing radiation in medicine. In addition to the NRC and the FDA, the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the Department of Energy (DOE) oversee exposure standards for the public and for workers. The transportation of radionuclides is regulated by the Department of Transportation (DOT). In some

cases, regulatory standards are established at the federal level but are administered by the states. Where federal oversight is absent, some states regulate independently in their roles as protectors of the public health and safety, but state laws and regulations often differ.

Nuclear Regulatory Commission

The Atomic Energy Act (AEA) of 1954 authorized the Atomic Energy Commission (AEC) (now the NRC) to regulate three particular types of ionizing radiation products: byproduct materials, source materials, and special nuclear materials. Byproduct materials used in medicine are subject to regulation under Title 10 of the Code of Federal Regulations (CFR) Part 35. Other forms of ionizing radiation used in medical products, however, such as radium, accelerator-produced materials, and machine-produced radiation were not included under the 1954 act and thus are not subject to NRC regulation. (They are, however, subject to FDA regulation, as discussed below.) The NRC regulates byproduct materials by directly licensing the manufacturers of byproducts used in radiation medicine and by approving the marketing of individual products containing those materials based upon an evaluation of their safety and effectiveness.

The NRC imposes strict control over medical use. Under the Medical Use Program (described below in greater detail), the NRC exercises licensing authority over the physicians who use byproducts and sets criteria for determining proper use. The NRC also has reporting requirements (that overlap with the FDA reporting requirements) in order to oversee its medical use standards. For other sources of ionizing radiation that are not subject to NRC jurisdiction, there is no parallel to the NRC's Medical Use Program. Thus, the use of *some* products in radiation medicine is very strictly controlled at the federal level while the medical use of *others* is regulated to varying degrees at the state level. At the federal level, these other radioactive products are subject to the general FDA policy that excludes medical practice from regulatory requirements for all drugs and devices.

The NRC's Medical Use Program. The NRC is responsible for regulating the "medical use" of byproduct materials. This responsibility, which the NRC carries out through its Medical Use Program, derives from the NRC's general responsibilities for protecting public health and safety in connection with nuclear reactors. All other medical uses and sources of ionizing radiation are regulated by other entities, such as the states or the FDA.[1]

[1] Boron neutron capture therapy, which does not involve byproduct material but rather uses radiation directly from a nuclear reactor to treat patients, is also regulated by the NRC.

Through the Medical Use Program, the NRC licenses facilities, authorizes physician users, develops radiation safety regulations, sets criteria for determining misadministration of byproduct materials in medical use, orders prompt reporting of misadministrations, conducts compliance inspections, applies a system of sanctions for infractions of its regulations, and assesses and collects fees and fines. The program is administered through two different systems. In 29 states ("Agreement States"), the NRC formally delegates authority to regulate byproduct material to the state government. In the remaining 21 states ("Non-Agreement States"), the NRC directly licenses, monitors, inspects, and enforces its regulations for approximately 2,000 licensed users and institutions.

Since World War II, the regulation of radiation medicine has intensified. In 1967, the NRC's predecessor, the AEC, codified its medical regulations into a new Part 35 of Title 10 of the CFR, called "Medical Use of Byproduct Material," which covered the medical use of both radioactive drugs and radiation devices. Although medical licensees are required to comply with many other sections of Title 10, Part 35 is the most important.

Part 35 contains provisions designed to protect patients and workers from devices, beams, and radiation sources. For example, to protect patients scheduled for radiation procedures, Part 35 requires implementation of quality management (QM) procedures (section 35.32) (see discussion below), a measurement of each dose prior to administration (35.53), a survey of the patient after removal of temporary implants (35.406), and safety checks of teletherapy machines and rooms (35.615). Other sections pertain to protection of the public and patients not scheduled for radiation procedures; these provisions include surveys before returning radiation areas to unrestricted use (35.315, 35.415), criteria for releasing patients who have received doses of radioactivity (35.75), and QM redundancy procedures for verifying patient identity (35.32).

The NRC oversees medical use licensees through its inspection, investigation, and enforcement programs. Inspections involve (1) unannounced visits by NRC personnel to each licensed facility on a periodic basis (ranging from once a year to once every four years depending on the scope of the license), and (2) special inspections to follow up a particular incident. Inspections are intended to assure that licensed programs are conducted in accordance with NRC requirements, with specific provisions of the license, and with the health and safety requirements of workers and the general public. NRC inspectors utilize direct observations of work activities, interviews with workers, and detailed reviews of licensee records to determine compliance with regulatory requirements.

Enforcement actions may be taken against licensees when violations of NRC regulations are discovered. Such violations range from failure to follow procedures detailed in a QM program to threats to public health and safety. Sanctions include more frequent inspections, release of negative publicity to the media, civil fines and penalties, and license revocation.

Misadministration rule. In 1968, six years before the Energy Reorganization Act split the AEC into two separate agencies, a patient died when exposed to 1,000 times the intended therapeutic dose of radioactive gold (Au-198). This error led the U.S. General Accounting Office (GAO) in 1972 to issue a report entitled *Problems of the Atomic Energy Commission Associated with the Regulation of Users of Radioactive Materials for Industrial, Commercial, Medical, and Related Purposes* (GAO, 1972). Noting the lack of information on overexposures, and tallying approximately 20 incorrect doses brought to the AEC's attention over the prior 10 years, the GAO criticized the AEC's "lax oversight" of byproduct material licensees. In response, the AEC proposed several revisions in its procedures. However, the AEC failed to act on the proposed revisions, which gradually faded into obscurity.

For several months in 1975 and 1976, a cobalt (Co-60) teletherapy unit was miscalibrated at the Riverside Methodist Hospital in Columbus, Ohio. During this period, almost 400 patients undergoing radiation therapy were overexposed by as much as 40 percent above the prescribed dose. By the time the error was reported, two patients had died as a direct result of the miscalibration. Over the next several months, eight additional deaths occurred that were probably attributable to the mistake. The NRC modified Riverside's byproduct materials license to require full annual calibrations, monthly spot checks, and detailed record keeping.

In 1979 the NRC extended these requirements to all Co-60 teletherapy licensees; it also implemented the GAO's 1972 recommendation that misadministrations of radiation be reported to the NRC and brought to the attention of the patient or family. This requirement was contested by physicians and professional organizations who considered it an intrusion into medical judgment and practice. Several states, however, endorsed the NRC's position of attempting to ensure greater protection of patient welfare, and the GAO supported the NRC by declaring that reporting of misadministrations would not constitute an intrusion into medical practice. After public hearings on the issue, the NRC issued a "Medical Policy Statement," which proposed three actions

- The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
- The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.
- The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine. (NRC, 1979)

In 1980 the NRC issued its rule on "Misadministration Reporting Requirements," which broadened reporting requirements to encompass both diagnostic and therapeutic procedures. The misadministration rule was incorporated into 10 CFR 35.41 and 35.45 and required licensees to (1) keep records of all misadministrations; (2) promptly (within 24 hours) report all therapy misadministrations to the NRC, referring physicians, and the patient or responsible relative or guardian; and (3) report diagnostic misadministrations quarterly to the NRC. The NRC estimated that the cost of the misadministration rule would be about $1.2 million, which it deemed reasonable if it saved even a single life.

A misadministration is defined by the NRC, generally, as the administration of some radioactive substance in an amount that exceeds by a certain percentage the prescribed dosage. The percentage calculation depends upon the substance in question. A misadministration may also be the administration of a correct dosage, but of the wrong substance, or to the wrong patient. (For the full definition of misadministration, see 10 CFR 35.2 in Appendix D.)

Over the following four years, NRC licensees reported 27 therapy misadministrations, or about 7 per year. Sixteen of these incidents involved teletherapy equipment; five, brachytherapy treatment; and six, radiopharmaceutical therapy. In analyzing these incidents, the NRC identified three basic causes: inadequate training, inattention to detail, and lack of procedural redundancy. The NRC, through its office for Analysis and Evaluation of Operational Data (AEOD) noted that

> although professional medical groups involved with radiotherapy and related government agencies encourage quality assurance programs in radiotherapy facilities, no government agency or non-governmental accrediting body requires that radiotherapy facilities have quality assurance programs that conform to the programs recommended by professional medical groups. Thus, many facilities may not have quality assurance programs that are consistent with recommendations of medical professional groups involved with radiation therapy. (AEOD, 1985)

The NRC instructed its Office of Nuclear Material Safety and Safeguards to:

- dispense the information contained in its report to affected licensees;
- contact appropriate professional organizations to encourage and support the initiation of a voluntary industry-directed quality assurance program for radiotherapy facilities;
- determine the effectiveness of the voluntary program within two years;
- consider the possibility of imposing a quality management rule if substantial progress toward completion of the voluntary program, including a final completion date, had not been demonstrated at the end of two years (AEOD, 1985).

In January 1986, Washington Hospital Center in Washington, D.C., reported that a patient was administered 150 rads of radiation with no request or desire for treatment from the referring physician. This event caused the NRC commissioners to direct staff to develop rulemaking that would initiate quality assurance (QA) programs to reduce the chance for therapy misadministrations. A year later the NRC published a proposed rule of "Basic Quality Assurance in Radiation Therapy" and an advance notice of proposed rulemaking, which called for a comprehensive QA program for any medical use of radioactive byproduct material. The NRC claimed that voluntary QA programs may not adequately assure public health and safety, but it limited the scope of the proposed prescriptive rule to radiation therapy and diagnostic procedures involving radioactive iodine.

These actions precipitated a major response from the medical community, including the recommendation that the proposed rulemaking should be performance-based rather than prescriptive. After several public hearings and discussions with medical organizations, the NRC published a proposal in 1990 for a new performance-based QM program and for revised recordkeeping and reporting requirements related to misadministrations. the NRC also announced that it would conduct a pilot program to evaluate the effectiveness of the proposed rule.

The NRC made a concerted effort to respond to critics of the 1990 proposed rule. In response to those who claimed that the rule would have little impact on reducing the already small number of misadministrations, the NRC emphasized that the number of reported therapeutic misadministrations in 1990 had increased to 24 from the average number of 10 for previous years. The proposed QM rule, it argued, was a legitimate regulatory response to a continuing problem in the use of radioactive byproduct material. Responding to critics who asserted that the NRC was duplicating standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the agency claimed that adherence to JCAHO standards is voluntary and that there is no guarantee that all licensees would implement a QM program.

Quality management rule. In January 1992, the NRC implemented the final version of its QM rule (NRC, 1992). The NRC's QM rule calls upon NRC licensees to establish a QM program in compliance with 10 CFR 35.32 and 35.33 if they administer radiation from sealed sources containing byproduct material for therapy (brachytherapy), if they administer cobalt teletherapy, or if they administer therapeutic unsealed radionuclides (therapeutic nuclear medicine) (see Chapter 2). The rule also applies to any diagnostic administration of greater than 30 microcuries of sodium iodide I-125 or I-131 (see Chapter 2 and Appendix D). Moreover, it requires NRC licensees to submit written certification that they have implemented a QM program. Whereas NRC licensees have been living with this rule since January 1992, Agreement States were not required to follow suit until January 1995.

The QM rule is a performance-based approach to quality management. This approach includes five specific objectives:

1. Prior to an administration, a written directive must be prepared.
2. Prior to each administration, the patient's identity must be verified by more than one method as the individual named on the written directive.
3. Final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery must be in accordance with the respective written directives.
4. Each administration must be in accordance with the written directive.
5. Any unintended deviation from the written directive must be identified and evaluated, and appropriate action must be taken.

The NRC Agreement State Program. The NRC Agreement State Program provides an opportunity for states to assume responsibility from the NRC to license and regulate byproduct material, source material, and small quantities of special nuclear material. NRC authority regarding radiological health and safety aspects of nuclear materials is transferred to the states through a formal agreement between the governor of the state and the NRC (Public Law 83-703, 1954). Currently, there are 29 Agreement States, and several other states are exploring agreement status.[2]

Use of the Agreement State arrangement requires that the NRC must conclude that a state's radiation control program "is compatible with the Commission's, meets the applicable parts of Section 274 [of the AEA] and … is adequate to protect the public health and safety." Once the state has passed enabling legislation to establish its authority to enter into the agreement, and its radiation control program is found to be both adequate and compatible with NRC requirements, state assumption of authority becomes effective on the date the agreement is signed.

Section 274j of the AEA stipulates, however, that the NRC may terminate or suspend all or part of an agreement with a state if it deems that such action is necessary to protect public health and safety. Although Agreement States administer their own programs and regulate licensees, the NRC maintains significant authority over the states. Biennially, the NRC's Management Review Board reviews each state's performance to determine whether its program is "adequate" and to ensure that its regulatory requirements do not significantly deviate from the NRC's.

Despite these reviews, NRC oversight of the Agreement State Program has been criticized for lacking data adequate for comparing the regulatory performance

[2] See Appendix E for a map and list of Agreement and Non-Agreement States. According to the NRC, four states have expressed an interest in becoming Agreement States: Oklahoma, Ohio, Pennsylvania, and Massachusetts (see Appendix E).

of NRC states with that of Agreement States. In April 1993, the GAO reported that the NRC lacks common performance indicators for inspection backlogs, radiation overexposures, and numbers of violations (GAO, 1993). Because the programs of NRC states and Agreement States use different indicators to measure effectiveness, the report asserts, the NRC cannot determine whether the public in each state is receiving the same minimum level of protection.

Partly in response to such criticism, the NRC amended and clarified its policies for overseeing the Agreement State Program. As of 1995, Agreement States are required to report data on misadministrations in the same form and using the same definitions as those used by the NRC for the Non-Agreement States. In May 1995, a new "Final Statement of Principles and Policy for the Agreement State Program" established a stronger performance evaluation process; it was intended to enable the NRC to take more effective, graduated actions to ensure that the radiation control safety programs of the Agreement States remain adequate and compatible (NRC, 1995). These actions include:

- periodically assessing Agreement State radiation control programs against established review criteria;
- providing assistance to help address weaknesses or areas within an Agreement State radiation control program requiring improvement;
- placing a state on a probationary status for serious program deficiencies that require heightened oversight;
- temporarily suspending an agreement and reasserting NRC regulatory authority in an emergency if an Agreement Sstate program experiences any immediate program difficulties that prevent the state from continuing to ensure adequate protection of the public health and safety; and
- suspending or terminating an agreement and reasserting NRC regulatory authority if the Agreement State experiences difficulties that jeopardize the state's ability to continue to ensure adequate protection of the public health and safety.

Food and Drug Administration

Biological drugs first became subject to federal premarket approval for safety and effectiveness under the Biologics Act of 1902, and the 1902 act remains basically unchanged to this day. The 1902 act was administered by the Public Health Service until it was transferred to the FDA in 1972.

The Pure Food and Drugs Act of 1906 imposed federal policing of all drugs (including biological drugs) to prevent adulteration or misbranding, but did not include premarket approval requirements. The 1906 act was replaced by the Federal Food, Drug, and Cosmetic Act of 1938, which required premarket notification (but not premarket approval) for the safety (but not the effectiveness) of new drugs (but not old drugs). The 1938 act was supplemented by the Drug

Amendments of 1962, following the thalidomide tragedy, to require premarket approval by the FDA of all new drugs for safety and effectiveness. The FDA is responsible for administering these statutes.

Medical devices were first made subject to general policing authority by the FDA to prevent adulteration or misbranding under the 1938 act. The 1938 act was supplemented by the Medical Device Amendments of 1976, which imposed premarket notification regarding the safety and effectiveness for most medical devices and premarket approval for safety and effectiveness for important new devices.

All radiation products were included within these statutory requirements for drugs and devices administered by the FDA. Thus, all of these laws, by their terms, required complete compliance by radiation products to the same extent and in the same way as any other drug or device.

Congress enacted the Radiation Control for Health and Safety Act of 1968 to provide additional regulatory authority for all "electronic products" that emit ionizing or nonionizing radiation, including medical products. The responsibility for administering the 1968 act was transferred to the FDA in 1971 and combined with the FDA medical device program in 1982.

The 1968 act also authorized the FDA to work with other federal and state agencies and private organizations to minimize exposure to electronic radiation. Pursuant to this authority, the FDA has issued guidelines and recommendations regarding public exposure to ionizing and nonionizing radiation.

Under the 1938 act, as amended for new drugs in 1962 and for medical devices in 1976, the FDA exercises direct authority to determine the safety and effectiveness, and to approve the marketing, of all radiation products used in medicine.[3] No radiation product may be investigated in humans without an investigational new drug (IND) application submitted to the FDA or may be marketed without FDA approval of a new drug application (NDA), a product license application (PLA) if it is a biological product, or one of two types of medical device approvals if it is a device. The FDA must review and approve the labeling of all of these products prior to marketing and must approve the manufacturing procedures for all of these products except medical devices that are substantially equivalent to previously marketed devices.

[3] Following enactment of the Drug Amendments of 1962, the NRC suggested that the FDA take over responsibility for approving the marketing of all new radioactive drugs, including those subject to NRC jurisdiction. The FDA declined to do this and, as an exercise of administrative discretion, exempted from its new drug approval requirements radioactive drugs approved for marketing by the NRC. In 1974, however, the FDA reversed itself, repealed the exemption, and thus took over from the NRC responsibility for determining the safety and effectiveness and approving the marketing of all radioactive drugs, including those containing materials that remained subject to an NRC manufacturing license and the NRC Medical Use Program.

After a radiation product is approved by the FDA for marketing, it remains subject to the same stringent postmarketing requirements as all other drugs and devices. The product must be manufactured in compliance with good manufacturing practices and is subject to drug and device reporting requirements with respect to product defects and adverse reactions.

Once a drug or device reaches the market, the FDA imposes surveillance and reporting requirements but does not in any way control the actual medical use of the product. Under a statement of policy first published in 1972 and since confirmed on several occasions, the FDA takes the position that physicians have the legal authority to use approved drugs and devices for unapproved uses. This policy applies to radiation products in the same way that it applies to all other drugs and devices.

Subsequent amendments to the Food, Drug and Cosmetic Act include the 1991 Safe Medical Device Act (SMDA). The SMDA requires that all institutions that use devices report all adverse events that occur due to equipment malfunction or defect or to user error. Determination of adverse events resulting in serious bodily injury is to be reported within 10 days to the device manufacturer and on a semiannual basis to the FDA. Deaths must be reported immediately to the FDA. The definition of a "device" is broad under the SMDA, but it does not cover pharmaceuticals or radioactive sources per se. However, equipment involved in the administration of radioactive sources and radiopharmaceuticals is subject to the reporting requirements.

Also, the FDA has been delegated the responsibility for implementing the Mammography Quality Standards Act (MQSA) of 1992. Under the MQSA, the FDA has promulgated regulations establishing quality control standards and a certification program for medical facilities that provide mammography services.

For those radiation products that are subject to both FDA and NRC jurisdiction, there are substantial overlapping regulatory requirements. A memorandum of understanding delineates the differences between the NRC's Medical Use Program and the FDA's procedures for approving pharmaceuticals (including radiopharmaceuticals) and devices (including radiation-emitting and radiation-producing devices). The FDA requires the registration of manufacturing establishments, and the NRC licenses these establishments. Both the FDA and the NRC separately approve the method of manufacture, require continuing compliance with good manufacturing practice requirements, and inspect the establishments to assure compliance, for the same radiation products. Both the FDA and the NRC, as already noted, also separately impose reporting requirements regarding adverse reactions for the same radiation products.

Finally, as discussed further below, for radiation products that are subject to FDA requirements but are not regulated by the NRC, a great majority of states have imposed their own controls with regard to medical uses. Although requirements imposed at the state level are not uniform throughout the country, there is

a trend toward uniformity based on the leadership assumed by the Conference of Radiation Control Program Directors.

Environmental Protection Agency

The EPA is responsible for the establishment and enforcement of environmental protection standards consistent with national environmental goals. It also has responsibility, once vested in the AEC and the Federal Radiation Council, for establishing radiation exposure criteria and standards.

Specifically, the EPA maintains active programs related to environmental radiation, monitoring sites around nuclear power plants, radioactive waste dumps, and areas of natural sources of radioactivity such as radon. A relevant example of EPA's standard setting is its 1978 guidance on medical x-rays. This guidance contained 12 recommendations that federal agencies were expected to implement. These covered several aspects of diagnostic medical and dental radiology, including the need for facilities to have QA programs for minimizing patient exposure during the production of diagnostic radiographs. Other recommendations dealt with qualifications of prescribers and specifications for techniques, fetal exposure, proper collimation, and gonadal shielding.

The EPA has also published guidance on topics such as occupational radiation exposure, and it has issued proposed guidance on radiation exposure for members of the general population. Although EPA has not proposed guidance for nuclear medicine quality assurance, it has the legal authority to do so.

States

States have broad authority and responsibility under the Constitution to protect citizens in matters of public health and safety. Most do so extensively, although specific laws and activities can and do vary considerably from state to state. With respect to the medical use of radiation, for example, states have authority to regulate the use of x-ray equipment in medicine and industry. They also have authority to regulate particle accelerators and naturally occurring and accelerator-produced radioactive material (NARM). States also license physicians and regulate the practice of medicine, certify and regulate supporting health professionals (such as x-ray technicians), and carry out broad public health responsibilities.

In the field of ionizing radiation in medicine, states regulate most diagnostic procedures, in that they regulate x-ray procedures. State also regulate roughly 90 percent of therapeutic procedures (see Chapter 1, footnote 6). They regulate all external beam therapy (teletherapy) except cobalt teletherapy, and they regulate some applications of brachytherapy and therapeutic nuclear medicine (those that employ NARM; most such procedures, however, employ NRC-regulated byproducts).

The states thus have by far the greatest share of regulatory responsibility for overseeing medical uses of radiation. The consensus view is that the smaller, NRC-regulated portion of the field—which concerns uses of byproduct materials—is more stringently regulated than the state-regulated portions, which concern uses of NARM and machine-produced radiation. This view is discussed in later sections of the chapter. Table 3.1 lists the states and indicates the type of regulatory programs in place in each. The unofficial Conference of Radiation Control Program Directors (CRCPD) data were collected for the Profile of State and Local Radiation Control Programs over a nine-year time span. The data are updated sporadically and do not necessarily reflect the current status of every state, because they have not been updated since 1993. Because no record of which changes were made in the 1993 data update exists, it is impossible to provide a date for when the information was obtained. In the "legislation" column, "mandated" indicates those states compelled to adopt regulations and implement programs (although this process can take a fair amount of time); "authorized" indicates that a state is authorized to adopt regulations and implement a program but is not required to do so. The "date" column refers to the date of the current statute, whereas the "original date" column indicates the date when the state first created a statute that addressed licensing and registration of NARM.

Although state laws, regulations, and administrative practices vary, states can and do achieve a level of uniformity in many areas through cooperative, voluntary, and informal arrangements. The most noteworthy example of such arrangements in the regulation of ionizing radiation is the publication called *Suggested State Regulations for Control of Radiation (SSRCR)*, which forms the basis for most state and local radiation protection programs. The *SSRCR* is a group of voluntary suggested guidelines prepared in the form of draft regulatory language available for state adoption. The *SSRCR* was first issued in 1962 by the Council of State Governments, with advice and assistance from the AEC and the U.S. Public Health Service. It has been regularly revised and updated to reflect changes in standards and technology and to incorporate changes in mandatory and voluntary federal regulations.

Today, these model regulations are prepared and published by the CRCPD. The CRCPD, established in 1968, is a not-for-profit network of state and local government radiation regulators. Although it has no independent regulatory authority, it is actively involved in information sharing and technical assistance activities. The CRCPD membership represents both NRC Agreement States and states directly regulated by the NRC; thus, it participates in implementing and providing feedback on NRC regulations. It was also involved, with the FDA and the American College of Radiology, in developing the MQSA and establishing the Nationwide Evaluation of X-Ray Trends program, which collects information and produces recommendations for planning and evaluating x-ray and computed tomography scan control programs.

Another nongovernmental organization that is influential in the regulation of ionizing radiation in medicine is the United States Pharmacopoeia (USP). Standards for all marketed radiopharmaceuticals are set out in USP's *National Formulary*. Monographs in the *Formulary* also set out acceptable uses for the substances, both labeled and otherwise. The USP standards are used by state pharmacy boards, by other professional medical societies, and by the FDA itself.

THE COSTS OF NRC REGULATION

This section examines the fee and non-fee costs of NRC regulation of ionizing radiation in medicine. The NRC supports its regulation of medical programs through the fees it charges licensees for licensing and inspections (NRC, 1994), and it imposes a variety of additional costs through its reporting and other requirements. It is important to note here that in Agreement States, all licensing of radioactive materials used in medicine is done by the state. In Non-Agreement States, NARM is licensed by the state while byproduct material is licensed by the NRC. Whether they are Agreement States or not, most states do not operate their licensing agencies like the NRC; their fees are generally lower than the NRC's fees. Licensees in Agreement States do not, in general, pay as much in fees as they would in states regulated by the NRC.[4]

In examining the costs of NRC regulation, this section addresses both cost recovery by the NRC through its fee collection process and the additional costs beyond license fees and fines ("non-fee costs") borne by NRC licensees. The discussion of non-fee costs reports the consensus view expressed to the committee about recordkeeping requirements, security requirements, and waste management policies. There is, in addition, some consideration of estimated cost savings to NRC licensees if certain NRC requirements were eliminated or revised.

This discussion of costs does not attempt to evaluate the financially unquantifiable costs associated with NRC medical use regulation, such as potential restrictions in access to medical care, impacts on choice of therapy, or other consequences of detailed NRC regulations. Nor does it attempt to quantify or detail the potential benefits of NRC regulation. The relative value of such regulation is discussed in the section on risk assessment in Chapter 4.

[4] Institute of Medicine staff attempted to obtain consistent, organized data on state fees. Apparently the CRCPD had made efforts in the past to collect this information. From 1978 to 1987 about 50 states contributed information on fees. During 1984–1992 approximately 30 states contributed partial information. One of the problems associated with collection of these data and any attempt to categorize the data for comparative purposes is that some states have as many as 60 categories of fees. Based on the difficulties encountered in collecting these data and the dwindling participation on the part of the states, an executive decision was made by senior staff at the CRCPD not to pursue collection of these data.

TABLE 3.1 Legislative Authority for Licensing and Registration of Naturally Occurring and Accelerator-Produced Radioactive Material

Radiation Control Program	Legislation	Current Statute	Date	Original Date	**Regulations Adopted**	Active Program
Alabama	Mandated	ACT 582	NP[a]	9/63	**Yes**	Yes
Alaska	Mandated	AS18.60.475-545	NP	1/78	**Yes**	Yes
Arizona	Mandated	ARS 30-672	1/80	1964	**Yes**	Yes
Arkansas	Authorized	ACA 20-21-214	1/88	1/61	**Yes**	Yes
California	Mandated	H&S 25815-25826	NP	1/61	**Yes**	Yes
Colorado	Mandated	25-11	NP	1/65	**Yes**	Yes
Connecticut	Mandated	222-148	NP	NP	**No**	No
Delaware	Mandated	16-7405	NP	1976	**Yes**	Yes
District of Columbia	Authorized	DC MR 20	NP	1/84	**Yes**	Yes
Florida	Authorized	F.S. 404.061	7/84	1964	**Yes**	Yes
Georgia	Authorized	CH. 31-13 OCGA	7/90	1/64	**Yes**	Yes
Hawaii	Authorized	HRS CH. 321	NP	NP	**No**	Yes
Idaho	Mandated	39-3000	NP	5/81	**Yes**	Yes
Illinois	Mandated	111 1/2-210-11	1990	7/59	**Yes**	Yes
Indiana	Mandated	26 13-1-2	NP	9/72	**Yes**	Yes
Iowa	Mandated	CH. 136C, IA CODE	4/84	6/79	**Yes**	Yes
Kansas	Mandated	48-1601 ET SEQ	NP	4/63	**Yes**	Yes
Kentucky	Mandated	KRS 211.842	6/78	3/60	**Yes**	Yes
Louisiana	Mandated	LRS 30:2105	6/84	6/84	**Yes**	Yes
Maine	Authorized	22 MRSA 677	NP	5/83	**Yes**	Yes
Maryland	Mandated	E ART. 8-301	NP	1967	**Yes**	Yes
Massachusetts	Authorized	CH. 111-SEC. 5B	NP	1/55	**No**	Yes
Michigan	Mandated	MCL 333.13515	NP	9/78	**Yes**	Yes
Minnesota	Mandated	144.12	NP	1/58	**Yes**	Yes
Mississippi	Mandated	AG'S OPINION	1/61	6/62	**Yes**	Yes

Missouri	Mandated	192.400-510	NP	1/64	**Yes**	Yes
Montana	Authorized	MCA 75-3-202	NP	1/67	**Yes**	No
Nebraska	Authorized	71:3501-3520	4/90	1/68	**Yes**	Yes
Nevada	Mandated	NRS 459	1/69	1/69	**Yes**	Yes
New Hampshire	Mandated	RSA 125-F:7	NP	5/66	**Yes**	Yes
New Jersey	Mandated	NJSA 26:2D-9.1	NP	1961	**Yes**	Yes
New Mexico	Authorized	74-3-1-16	NP	1/74	**Yes**	Yes
New York	Mandated	10NYCRR Part 16	NP	9/55	**Yes**	Yes
North Carolina	Authorized	GS 104 E-7	NP	1/63	**Yes**	Yes
North Dakota	Mandated	23-20.1-03,04	7/65	7/65	**Yes**	Yes
Ohio	Mandated	ORC 3701.912	NP	3/85	**Yes**	Yes
Oklahoma	Authorized	63 O.S.SUPP '81	NP	4/69	**Yes**	Yes
Oregon	Authorized	453.605 to 745	NP	1/65	**Yes**	Yes
Pennsylvania	Mandated	ACT 1984-147	7/84	7/84	**Yes**	Yes
Puerto Rico	None	None	NA[b]	NA	**No**	No
Rhode Island	Mandated	23-1.3	NP	5/76	**Yes**	Yes
South Carolina	Mandated	13-7-40	NP	1/76	**Yes**	Yes
South Dakota	Authorized	34-21-18	NP	1/67	**Yes**	Yes
Tennessee	Mandated	TCA 68 CH. 23	7/88	1/59	**Yes**	Yes
Texas	Mandated	HSC CH. 401	1989	4/61	**Yes**	Yes
Utah	Authorized	UC 26-1-27	NP	7/81	**Yes**	Yes
Vermont	Authorized	18/VSA. S1651-1657	NP	1/77	**Yes**	Yes
Virginia	Mandated	32.1-229	NP	1/79	**Yes**	Yes
Washington	Mandated	RCW 70.98	NP	7/61	**Yes**	Yes
West Virginia	Mandated	CH. 16-ART.1	NP	5/79	**Yes**	Yes
Wisconsin	Mandated	140.50-61	NP	7/79	**Yes**	Yes
Wyoming	None	None	NA	NA	**No**	No

[a] Not Provided.
[b] Not Applicable.
SOURCE: Unofficial CRCPD data collected for the *Profile of State and Local Radiation Control Programs*; personal communication from Terry Devine, Conference of Radiation Control Program Directors, January 16, 1995.

Cost Recovery by the NRC Through Fee Collection

The easiest costs to tabulate are those directly assessed by the NRC through fees and fines. As authorized by Congress, the NRC must recover virtually its entire annual budget from various fees. In 1994, it recovered approximately $513 million, which was 100 percent of its $535 million budget authority less $22 million appropriated from the Department of Energy's Nuclear Waste Fund (NRC, 1994).[5]

The NRC assesses two basic kinds of fees: (1) license and inspection fees for individually identifiable services established in 10 CFR Part 170; and (2) annual fees, established for generic and other regulatory costs established in 10 CFR Part 171. The NRC collects both license and inspection fees and annual fees for 57 specific categories of materials licenses (in addition to nuclear reactor facilities). The most relevant categories to medical use are licenses for human-use, including "teletherapy," "broad scope medical," and "other medical" licenses (see Table 3.2, below). The NRC operates under a congressional mandate that, "to the extent practicable, a class of licensees bear the costs of providing regulatory services to them."

Cost of a Full-Time Equivalent at NRC

Each year, the NRC publishes its fee schedule for the next fiscal year (FY) in the *Federal Register* in the form of proposed rulemaking for 10 CFR Parts 170 and 171. The numbers that follow are derived from the 1994 proposed rulemaking (NRC, 1994). The NRC considers 1,628.9 of its 3,223 full-time-equivalent employees (FTEs) (50.5 percent) to be in direct support of non-Nuclear Waste Fund programs. The remaining FTEs are considered overhead and general and administrative personnel (NRC, 1994). The work of the direct-support FTEs represents $376.6 million of the NRC's total operating budget;

[5] On June 21, 1995, the NRC issued a press release that read, in part, as follows:

The Nuclear Regulatory Commission is making changes to the licensing, inspection and annual fees it charges applicants and licensees. …

The Commission's budget authority for fiscal year 1995 is $525.6 million, of which about $22 million has been appropriated from the Nuclear Waste Fund, leaving approximately $503.6 million to be recovered from fees. This is about $9.4 million less than the total amount to be recovered for fiscal year 1994 and $15.3 million less than in fiscal year 1993. …

As a result of the reduced budget amount to be recovered …, the annual fees for a large majority of licensees will be reduced: …

— for radiography licensees to $13,900 from $19,200; and

— for broad scope medical licensees to $23,200 from $32,600.

TABLE 3.2 Fee Schedule for Selected Materials License Categories for FY 1994

Category of Materials License	10 CFR Part 170				10 CFR Part 171	
	Application/ New License	Renewal	Amendment	Inspections	Annual Fee	Surcharge
Human-Use Licenses: Direct Costs						
7A (Teletherapy)	$3,700	$1,200	$560	$2,300	$16,900	$170
7B (Broad scope medical)	$2,700	$3,500	$500	$8,700	$30,900	$1,670
7C (Other medical)	$1,100	$1,400	$500	$2,100	$5,900[a]	$170[a]
Other Selected Licenses: Indirect Costs						
3C (Processing/manufacturing and distribution /redistribution)	$3,500	$3,000	$490	$3,400	$12,000	$1,670
3D (Distribution/redistribution only)	$1,300	$550	$370	$3,000	$6,000	$170
4A (Waste disposal)	Full cost	Full cost	Full cost	Full cost	$130,200	$1,670
4B (Waste packaging)	$4,000	$2,100	$430	$2,300	$16,400	$1,670
4C (Waste brokering)	$1,500	$1,100	$250	$2,800	$7,500	$1,670
17 Master materials licenses of broad scope issued to government agencies	N/A	N/A	N/A	N/A	$430,500	$22,970

NOTE: N/A = not applicable. License categories 3C and 3D deal with processing and manufacture, and distribution and redistribution, of radiopharmaceuticals, generators, reagent kits, and/or sources and devices.
SOURCE: Strom, 1995.
[a] A private practice physician may qualify as a "small entity" under 10 CFR 171.16(c), with a cap on costs that depends on gross annual receipts (GAR): for GAR $250,000 to $1,000,000, the "maximum annual fee per licensed category" is $1,800; for GAR less than $250,000, $400.

thus, one FTE represents $231,199 annually. Using the figure of 1,744 productive hours per FTE per year, the cost of an FTE-hour to be passed along to licensees is $133.

- for radiography licensees to $13,900 from $19,200; and
- for broad scope medical licensees to $23,200 from $32,600.

To arrive at fees for particular licensing activities, the NRC may use historical average number of hours spent (e.g., reviewing a category of license application or processing a particular license amendment) or it may bill on the basis of actual staff hours consumed by the activity. For nonroutine services, the NRC generally records the number of hours expended. The NRC multiplies the resultant number of hours by $133 to arrive at the amount to be paid by the licensee or license applicant. For an eight-hour day, the corresponding rate would be $1,064.

Fee Schedules for Selected NRC License Categories

As stated above, the NRC has established 57 categories of materials licenses. Table 3.2 shows FY 1994 fee schedules for selected categories relevant to medical use. Categories 7A (teletherapy), 7B (broad scope medical), and 7C (other medical) are human-use categories. Fees from these categories appear *directly* in the cost of using NRC-licensed materials in medicine.

Fees from many of the other categories appear *indirectly* in the cost of using NRC-licensed materials in medicine. These categories include licenses involved in processing and manufacturing, and distribution or redistribution, of radiopharmaceuticals, generators, reagent kits, and/or sources and devices (categories 3C and 3D), and for waste disposal activities (categories 4A, 4B, and 4C, which are attributable only in small part to medical uses). Other categories whose fees appear as indirect costs include irradiator licenses, calibration licenses (for instruments and equipment), transportation licenses, and import and export licenses.

By far, the highest costs are the fees levied annually. Annual fees shown in Table 3.2 for the human-use licenses range from $5,900 to $30,900. For comparison, a typical nuclear power reactor pays an annual fee upwards of $3 million.

Fees Collected from Selected NRC License Categories in 1993

The fees actually collected by the NRC in FY 1993 are listed in Table 3.3 for human-use categories. Combined, all human-use licensees paid more than $14 million in various fees in FY 1993.

Fines Collected from Selected NRC License Categories in 1993

Fines collected by the NRC go directly to the U.S. Treasury, not to the NRC. Such fines are imposed only upon the small fraction of licensees who have

TABLE 3.3 Fees Collected by the NRC in FY 1993, by Selected Materials License Category

Category of Materials License	Applications	No.	Amendments	No.	Re-newals	No.	Inspection Fees	No.	Annual Fees	No.	Row Totals
Human-Use Licenses											
7A (Teletherapy)	$3,600	1	$24,390	62	$27,935	38	$116,602	53	$2,055,691	151	$2,228,218
7B (Broad scope medical)	$3,360	2	$14,620	39	$9,130	4	$76,691	9	$2,392,663	116	$2,496,464
7C (Other medical)	$71,500	89	$392,938	963	$323,530	321	$620,253	295	$7,931,590	1,506	$9,339,811
Totals	$78,460	92	$431,948	1,064	$360,595	363	$813,546	357	$12,379,944	1,773	$14,064,493

[a] Full cost fees.

SOURCE: Strom, 1995.

committed serious violations. Summary data on fines for FY 1993 are shown in Table 3.4.

Relatively few licensees paid fines (30 of 1,773), and the total direct cost of fines was only 1.1 percent of the direct cost of the fees.

Whenever the NRC levies a fine, the agency also sends a press release to print and broadcast media in the licensee's area describing the violation and the fine. It is difficult to quantify the adverse economic impact on licensees of the press releases that accompany fines from the NRC, but the licensees assert that the impact is considerable.

Non-Fee Costs of NRC Regulation

To assess the non-fee costs of NRC regulation that are borne by licensees, the committee authorized a limited telephone canvass of radiation safety officers (RSOs)[6] at several NRC broad scope (category 7B) licensees (see discussion of license categories above). (Most of the respondents represented licensees that had category 7A licenses as well.) The RSOs were selected because they represented medical schools and hospitals with large research and clinical programs (inpatient and outpatient nuclear medicine and radiation therapy departments); the institutions represented three of the NRC's four geographical regions.

The information from this source, together with information from site visits and testimony heard by the committee, showed widespread agreement among interviewees and witnesses about three areas of regulation that represent non-fee costs: recordkeeping requirements, security requirements, and waste disposal policies. These are discussed in more detail below.

Recordkeeping Requirements

All RSOs and most other interviewees felt that NRC recordkeeping requirements are excessive. They also believed that enforcement actions are sometimes out of line with the degree of seriousness of minor omissions, errors, or gaps in records. Procedures for dealing with "package surveys" were cited as one example of excessive requirements. All but one of the licensees contacted stated that their current procedures for package receipt, log-in, and survey would be dropped if they were not required by provisions at 10 CFR 20.1906. One licensee said that 60,000 packages had been surveyed in the past 20 years, with not

[6] RSOs are professional support personnel who design, write licenses for, and operate radiation safety programs, and they deal with the NRC directly. Medical personnel such as physicians, nuclear medicine technologists, radiation therapy technologists, and nuclear pharmacists generally have different interactions with the NRC and different kinds of duties. The RSOs in general have a very broad view of the NRC's regulation of medical programs, but with a less clinical perspective than the principal care givers.

TABLE 3.4 Fines Collected by the NRC in FY 1993, by Selected Materials License Category

Category of Materials License	Total Fines Paid	Number of Fines	Average Fine Paid	Number of Licensees	Percentage Paying Fines	Total Fees Paid	Fines as a Percentage of Fees
7A (Teletherapy)	$33,250	3	$11,083	151	2.0	$2,228,218	1.5
7B (Broad scope medical)	$20,000	2	$10,000	116	1.7	$2,496,464	0.8
7C (Other medical)	$104,425	25	$4,177	1,506	1.7	$9,339,811	1.1
Totals	$157,675	30	$8,420	1,773	1.7	$14,064,493	1.1

NOTE: License categories 3C and 3D deal with processing and manufacture, and distribution and redistribution, of radiopharmaceuticals, generators, reagent kits, sources and devices. SOURCE: Strom, 1995.

one incident of leakage or damage. Several RSOs pointed out that manufacturers have had, since the late 1970s, excellent packaging practices that obviate the need for such strict receipt, log-in, and survey practices.

The QM rule, instituted for NRC licensees in 1992 and required for Agreement States in 1995, was cited as another example of overregulation. Many RSOs and professional groups believe that benefits derived from the QM program are outweighed by the costs of maintaining a prescriptive regulatory program. None of the RSOs contacted believed that the QM programs and enough value to justify the level of recordkeeping that is required.[7]

Security Requirements

The committee found universal agreement among interviewees and witnesses that in the recent past the NRC has excessively tightened its enforcement of provisions meant to ensure the safekeeping of byproduct material (10 CFR 20.1801 and 20.1802). Typically, a licensee secures radioactive materials under lock and key when they are not attended, but in the past this had been interpreted as covering evenings and weekends, not the course of a workday. In several instances in NRC Region I, RSOs reported that their programs have been cited, fined, and threatened with enforcement conferences at regional headquarters for innocuous, if widespread, violations of security in research laboratories and nuclear medicine departments. The violations in question involved leaving small quantities of unsealed radionuclides unattended in laboratories, although they were always clearly marked as dangerous radioactive material.

The significance of this can be considered in terms of the annual limit on intake (ALIs), which is the quantity of each radionuclide in a particular chemical and physical form that, if ingested (or inhaled), produces an effective dose equivalent of 5 rems. The NRC's annual dose equivalent limit for the general public is 0.1 rem. The quantities in question for these licensees were on the order of 1 to 10 ALIs. By way of comparison, a common household smoke detector, which sits in many homes, typically contains 0.9 microcuries (μCi) of americium-241 (Am-241). The inhalation ALI of Am-241 is 0.01 μCi (10 CFR Part 20,

[7] On December 24, 1991, the NRC submitted an information collection request to the Office of Management and Budget (OMB), as required under the Paperwork Reduction Act. The request sought authorization to require recordkeeping under the QM rule. The OMB denied the request, citing the low incidence of adverse events. Although the OMB was unable to determine with any accuracy the burden that would be imposed by the requirements (with estimates ranging from 20,000 to 200,000 extra hours per year), it felt that any burden was unreasonable, given its finding that "reporting and recordkeeping requirements will have little if any practical utility furthering the goal of reducing injuries from misadministrations" (MacRae, 1992). A majority of the NRC's commissioners voted to override the OMB denial, using a provision within the Paperwork Reduction Act that allows independent regulatory agencies to do so.

Appendix B, Table 1, Column 2). Such smoke detectors, therefore, contain 90 ALIs and, if leakage occurs, may produce an effective dose equivalent of 450 rems. This serious dose would be 4,500 times the NRC's limit.

The committee did not find any challenge to the need for tight security for large, life-threatening sources. The point of the interviewees' and witnesses' observations was that a graded approach is needed to keep the regulatory requirements and response in line with the hazards. Radiation hazards, interviewees and witnesses also pointed out, must be viewed in the context of laboratories that safely use other, far more hazardous chemical, biological, and physical agents without the need for such tight security regulations.

According to the RSOs and many practitioners interviewed during site visits, the recently tightened security enforcement has caused researchers and subspecialists to conclude that the NRC and its inspectors are overly zealous, and that their actions impede both patient care and research. The RSOs stated that, as a result, respect for NRC employees and regulations suffers among scientists and clinicians who understand the relative hazards. Several RSOs stated that regulations and procedural requirements that are "clearly out of line with common sense" erode the collaborative relationship between radiation protection staff and users of licensed materials; for this reason, these experts believe that such stringent requirements and aggressive enforcement strategies may ultimately reduce rather than heighten safety.

Radioactive Waste Management

There was general consensus among interviewees and witnesses that the difficulty and expense of waste disposal have driven up costs and eliminated some benefits of the use of NRC-licensed materials. All RSOs stated that radioactive waste management policies had had severe impacts on themselves, on the users of licensed radioactive materials, and on the kinds of patient care and research being performed in their institution. Some said that procedures generating waste that could not be held for decay were being abandoned because nothing could be done with the waste except store it. One licensee stated that a building for waste storage had just been completed at his facility at a cost of $1 million; another licensee indicated that the budget for waste disposal at his institution was $750,000 for FY 1995.

These increased costs were attributed in part to NRC requirements that are not risk based. RSOs pointed out that the NRC will not deregulate licensed material even after it decays to concentrations that are below concern. Byproducts with half-lives of less than 65 days are the exception to this statute, because they shift eventually to a "below regulatory concern" category. Such below regulatory concern (BRC) concentrations are listed in 10 CFR Part 30 for many nuclides. All RSOs agreed that medical uses of NRC-licensed materials would benefit from a BRC policy and that, if such a policy were put in place, safety would not

decrease. Such a policy, it was believed, would dramatically decrease waste disposal costs, and this in turn would reduce the overhead of radiation safety programs. The BRC policy has been surrounded by political controversy between congressional representatives and the NRC for a number of years. Consequently, the NRC is not working on implementation now.

Cost Savings Estimates for Some NRC Licensees

RSOs from four NRC licensees were asked how many personnel could be eliminated if NRC regulations were revised to eliminate tasks such as package receipt, log-in, and surveys, unneeded and unproductive recordkeeping, inconsistent waste disposal provisions, time-consuming licensing and inspection programs, and high fees. Three RSOs estimated savings of 1 FTE, and one estimated savings of 2.5 FTEs. In addition, the RSO for one licensee estimated that 0.5 FTE would be eliminated in the nuclear medicine department. The RSO estimates are shown in Table 3.5.

These estimates are clearly speculative. Developing more exact estimates would entail enormous difficulties and effort, and the results would still be approximate. Estimated savings in salaries ranged from about $42,000 to $150,000 annually (not including nuclear medicine), generally comparable to total license fees. Estimated FTE savings ranged from 3 to 15 percent of each overall budget.

As suggested earlier, a full assessment of the relative value of NRC regulations cannot examine only costs and administrative burdens. It must also analyze the relative risks posed by ionizing radiation and the benefits of NRC regulations in reducing those risks. That subject is examined in more detail in Chapter 4.

Summary of Fee and Non-Fee Costs of NRC Regulation

In 1993, the average teletherapy licensee paid NRC fees of nearly $15,000; the average broad scope medical licensee paid about $21,500; the average small medical licensee, about $5,000; the average manufacturer or processor, $14,293; and the average distributor or redistributor, about $5,500. Large licensees pay well in excess of twice these fees. Three broad scope licensees estimated savings of more than twice the amount of fees they paid if NRC regulations were, in their view, brought into line with the risks being regulated. These licensees all concluded that, if NRC regulations were revised, they could reduce their safety and compliance programs considerably while still maintaining the same degree of protection for workers, patients, the public, and the environment.

TABLE 3.5 Savings Estimated from Projected Reduction at Four NRC Licensees

Inst.	Region	Dept.	Annual Budget	Number of Separate Licenses at Institution	Total Costs	Salary as a Percentage of Budget	FTEs	Staff Time on NRC Reg. (%)	FTEs that Could Be Eliminated	Savings	Savings as a Percentage of Costs
A	1	RSO	$650,000	3	$700,000	60	9	43	1.0	$43,333	7
B	1	RSO	$1,000,000	3	$1,000,000		16	25	2.5	$150,000	15
C	2	RSO	$500,000	1	$500,000	70	7	36	1.0	$50,000	10
C	2	Nuc. Med.	N/A	1	N/A	N/A	N/A	N/A	0.5	$30,000	?
D	3	RSO	$1,316,828	7	$1,316,828	51	16	20	1.0	$42,000	3

NOTE: Dept. = department; Inst. = institution; med. = medicine; N/A = not available; Nuc. Med. = nuclear medicine SOURCE: Strom, 1995.

With respect to non-fee costs, several criticisms of current NRC regulations emerged from interviews with RSOs and others. To save money without compromising safety, it was believed, the NRC should relax:

- package receiving and opening requirements;
- security requirements for small amounts of activity;
- recordkeeping requirements;
- enforcement actions for minor infractions; and
- waste disposal requirements that are not risk based.

QUALITATIVE ASSESSMENTS OF NRC REGULATIONS

As described in Chapter 1, the committee's fact-finding efforts included eliciting information from individuals and organizations via a public hearing, a technical panel comprising health professionals, and site visits to various medical institutions and state organizations in the states of Georgia, Minnesota, Massachusetts, and California. Many of the experts from whom the committee heard believed that over the past two decades, NRC regulation had helped bring a high level of quality and accountability and had provided some useful services to radiation medicine. Several criticisms emerged, however, of current NRC regulation of medical programs.

The committee notes that these criticisms are difficult to substantiate quantitatively because of the lack of adequate data, particularly with regard to risk assessment. A detailed examination of risk assessment is reserved for Chapter 4. Within the scope of the present chapter, however, the committee underscores the fact that the reported incidence of misadministrations of byproducts is low, which may or may not be attributable to the NRC regulatory structure now in place. As to state-regulated radiation, the committee is not aware of data on the rates of misadministrations traceable to NARM or machine-produced radiation, or reports of unusual sources or serious incidents.[8]

Criticism of the Regulatory System

The criticism that emerged from the committee's interviews among the regulated community and other information-gathering efforts led the committee to reflect on specific aspects of the regulatory system. Among these aspects are the fragmentation and intensity of regulation according to radiation source; the administrative burdens; the NRC fees and fines; and the increasing burden and unwarranted detail of NRC inspections.

[8] In one area of state-regulated radiation, namely, fluoroscopy, a pattern of misadministration has been identified; this was addressed through an FDA alert (FDA, 1994).

Fragmentation and Disproportionality

Fragmentation of regulation and the difference in detail and intensity between state and federal regulations were cited by the regulated community. Along with the "fracture" that gives the NRC responsibility for byproduct material while leaving regulation of NARM and machine-produced radiation to the states, the disproportion between the two levels of regulation leads to needless upgrading of requirements for state-regulated activities. In one example, a radiation safety officer, for fear of establishing two separate standards of medical care, one for NRC-regulated activities and another for state-regulated activities, applies NRC standards throughout his institution, resulting in massive costs for additional linear accelerator shielding and the extension of the NRC-mandated QM program. In another example, a university hospital plans all radiation therapy, the majority of which employs a linear accelerator, according to 10 CFR Part 35 requirements, just in case the accelerator fails and the patient must be switched to the cobalt unit.

An additional problem, related to fragmentation, concerned the lack of communication among the federal agencies (FDA, EPA, OSHA, DOT) responsible for overlapping aspects of radiation protection. This lack of communication occurs despite formal memoranda of understanding between some of the agencies. This situation is exemplified in the GAO report *Nuclear Health and Safety: Consensus on Acceptable Radiation Risk to the Public Is Lacking* (GAO, 1994). The report examined whether existing radiation protection standards provide a coherent, complete federal framework for public protection. The GAO found large disparities in the standards established by different agencies and no consensus emerging on what those standards ought to be. Most importantly, the GAO found that at least 26 different draft or final federal radiation standards or guidelines contain specific radiation limits, some of which differ numerically from others. Table 3.6 illustrates these disparities.

Administrative Requirements

The NRC's administrative requirements are an area of concern. 10 CFR 35.20, for example, presents the concept of "as low as reasonably achievable" (ALARA) as a regulatory process. ALARA guidelines issued by the NRC are treated not as an operational philosophy but as enforceable standards. Section 35.21 sets out strict procedures for routine monitoring of everything associated with radioactivity, from receiving and opening packages to keeping records in a

TABLE 3.6 Federal Radiation Exposure Limits

Standard or Guideline/Agency	Type/Effective Date	Limit	Estimated Lifetime Risk of Premature Cancer Death[a]
General Standards/Guidelines			
1. General public/NRC	Regulation (10 CFR 20), 1993	0.1 rem/yr	
2. General public/EPA	Guidance, 1960	0.5 rem/yr	
3. General public/EPA (draft)	Proposed guidance	0.1 rem/yr	
4. General public/DOE (draft)	Proposed regulation (10 CFR 834)	0.1 rem/yr	
Source-Specific Standards/Guidelines			
5. Uranium mill tailings/NRC	Regulation (10 CFR 40), 1985		
		Radium-226: 5 pCi/g	1 in 50[b]
		Radon: 20 pCi/m2s	1 in 14,000[c]
6. Drinking water (interim)/EPA	Regulation (40 CFR 141), 1977	Beta/photon:[d] 0.004 rem/yr	
6a. Drinking water (draft)/EPA	Proposed regulation (40 CFR 141)		
		Radium: 20 pCi/l	
		Radon: 300 pCi/l	
		Beta/photon:[d] 0.004 rem/yr	
7. Uranium fuel cycle/EPA	Regulation (40 CFR 190), 1979-1983	0.025 rem/yr	
8. Spent fuel, high-level, transuranic waste disposal/EPA	Regulation (40 CFR 191), 1994		
		All pathways: 0.015 rem/yr	
		Groundwater: 0.004 rem/yr[d]	

		Containment: 1,000 deaths in 10,000 yrs	
9. Uranium mill tailings/EPA	Regulation (40 CFR 192), 1983		
		Radium 226: 5 pCi/g	1 in 50[b]
		Radon: 20 pCi/m2s	1 in 14,000[c]
Occupational Standards/Guidelines			
10. Occupational/NRC	Regulation (10 CFR 20)	5 rem/yr	
11.Occupational/EPA	Guidance, 1987	5 rem/yr	
12. Radon in uranium mines/EPA	Guidance, 1971	4 WLM/yr[e]	
13. Occupational/DOE	Regulation (10 CFR 835), 1993	5 rem/yr	
14. Under-ground mines/MSHA[f]	Regulation (30 CFR 57), 1977	Radon: 4 WLM/yr	
15. Occupational/OSHA	Regulation (29 CFR 1910.96), 1971	5 rem/yr	

[a] For purposes of comparison, the estimated risks in the table are derived from commonly used assumptions (e.g., a cancer death risk of 5 × 10-4 per rem to an individual continuously exposed over a 70-year lifetime; for workers, 50-year exposure). The estimated risks may differ from those derived by agencies, which used various assumptions in setting standards and guidelines. Some estimated risks are to individuals, and others are to larger defined populations. Risks are rounded.

[b] Based on exposure to an individual residing on-site after cleanup. The estimated risk to an individual off-site could be considerably less.

[c] Based on average population exposure. According to EPA and DOE, the estimated risk to a maximally exposed individual could be considerably greater.

[d] Beta particle and photon radioactivity from man-made radionuclides in community water systems.

[e] WLM = working level month, equivalent to about 100 pCi per liter of radon in equilibrium with its progeny for 170 hours of worker exposure.

[f] MSHA = Mine Safety and Health Administration

NOTE: g = gram; l = liter; m^2 = square meter; pCi = picocurie; s = second.

SOURCE: Adapted from GAO, 1994.

form acceptable to NRC inspectors.[9] Much time, effort, and money is spent satisfying such administrative demands.

Perhaps the greatest attention went to the quality management and notification requirements set out in sections 35.32 and 35.33. The consensus among the technical panel representatives, interviewees at medical institutions, and those who spoke at the public hearing was that elimination of the QM rule would not lessen the radiation protection of the public, the occupational worker, or the patient. The committee shared this opinion, based on members' experience, expertise, and the results of their findings.

Finally, the committee recognized that the patient notification requirement in 10 CFR 35.33 was particularly controversial, even within the NRC itself, and will have negligible marginal positive effects and generally negative effects, when seen in the context of usual medical practice and monitoring

Fees and Fines

NRC fees and fines were identified as excessive for the amount of risk posed by the use of radionuclides in medicine. Fees and fines were cited as one of the main reasons that Non-Agreement States are becoming Agreement States. Several individuals interviewed during site visits voiced concern that excessive costs force laboratories to stop using radionuclides, which in turn delays or prohibits the development and implementation of new uses of radionuclides in medicine. Boron neutron capture therapy was given as one example of a new technology whose development and diffusion is impeded by the costs of NRC regulation. In addition, many individuals in the regulated community objected to the NRC's budget being funded solely through licensing and enforcement fees. In no case did any of the RSOs interviewed believe that they receive value or services from the NRC that are commensurate with the fees they pay.

CHAPTER SUMMARY

This chapter has set out the costs, economic and otherwise, of the current system of regulating ionizing radiation in medicine. Regulation always has its costs, but they must be weighed against any benefits derived, such as the protection

[9] Chapters 1245 and 1246 pertaining to inspector qualifications and materials license reviewer qualifications include the following language: "They must also be keenly aware of the potential for negative impact on safety if the inspection process is allowed to become overly intrusive in areas of licensee operation where problems are not occurring" (NRC Inspection Manual, 9/91, p.1). "The reviewer must also become aware of the possibility of his/her inadvertently handicapping the licensee's activities by imposing unreasonable or unnecessary license conditions" (NRC Inspection Manual, 2/94, p.1). The regulated community asserts that these policies are not heeded. The committee gathered much detail on such instances.

of public health and safety. The next chapter explores the risks of using ionizing radiation in medicine, to determine whether a problem exists that necessitates regulatory intervention.

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4

Risks of Ionizing Radiation in Medicine

The discussion of the regulation of radiation medicine in Chapter 3 concluded with an account of beliefs and attitudes about regulation that the committee found to be prevalent within the regulated community. One common theme was that the Nuclear Regulatory Commission (NRC) regulatory requirements are out of proportion to the risks involved. The present chapter brings to the forefront the issues of what the risks of ionizing radiation are estimated to be and how this issue is currently addressed in the exercise of regulatory authority.

The chapter opens with a general discussion introducing the concept of risk assessment and the conceptual model currently used by U.S. regulatory agencies as a matter of public policy to assess the risk of exposure to low-level radiation (the "linear, no-threshold" model). The next section addresses risk from a different standpoint: the likelihood that unintended exposures will occur as the result of error or accident in the medical use of ionizing radiation. Finally, the third section addresses the public's perception of risk.

RISK ASSESSMENT

For the purposes of this report, human health risk assessments include the evaluation of scientific information about (a) hazardous properties of radiation and radioactive materials and (b) the extent of human exposure to these agents. These risk assessments provide estimates of the probability that exposed populations will be harmed and to what degree. The probability may be expressed either quantitatively or qualitatively; it is typically arrived at through an analytic

process such as the four-step process described in *Science and Judgment in Risk Assessment* (NAS/NRC, 1994):

1. Hazard Identification: Identification of the potentially hazardous agent and a description of the specific forms of toxicity that may be expressed in exposed populations.
2. Dose-Response Assessment: Evaluation of the conditions under which an agent may be toxic and an evaluation of the quantitative relationship between the dose and the toxic response.
3. Exposure Assessment: Specification of the population that might be exposed, identification of the routes by which exposure can occur, and estimates of the magnitude and duration of exposure that people are likely to receive.
4. Risk Characterization: Development of a qualitative or quantitative estimate of the hazards associated with the agent that will be realized in exposed people. This includes a full discussion of the uncertainties associated with the estimates of risk.

In the case of risks of exposure to radiation at low levels (less than 0.1 gray (Gy) effective dose equivalent delivered instantaneously or less than 0.2 Gy delivered at a low dose rate), the scientific uncertainty about negative side effects, such as long-term cancer, is considerable. Radiogenic cancer (i.e., neoplasms caused by exposure to ionizing radiation) has not been observed in humans at low levels of exposure, and it is unknown whether such negative sequelae to diagnosis actually exist. If they exist, it is beyond the range of current science and medicine to observe and measure them.

Because of this scientific uncertainty, a public policy decision has had to be made regarding what approach to use in setting standards for protection of individuals against potential problems secondary to low-level exposures to radiation. U.S. regulatory agencies currently use a model that describes radiation injury as a linear function of radiation dose that has no lower threshold; this is called the linear, no-threshold model. Scientific consensus groups, including the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and a National Research Council Committee on the Biological Effects of Ionizing Radiation (BEIR), have also endorsed the use of this model for risk assessment (see NCRP, 1987; NAS/NRC, 1990; ICRP, 1991). This approach reflects an understandable tendency to be conservative in choosing analytical models that emphasize public safety.

In the linear, no-threshold model, data from high levels of exposure (greater than 0.5 Gy effective dose equivalent), where some radiogenic cancers have been observed in humans, are extrapolated to low levels of exposure, where radiogenic cancer has not been observed. The model can then be used to predict the risks of cancer at various levels of exposure; it specifically predicts very

small but finite risks, at low-level exposure. One result of this predicted likelihood of very small but finite risk is that, if it is multiplied by a large number (for example, the population of the United States), it produces an estimate of a finite number of radiation-induced cancer deaths—even though whether such deaths actually occur is unknown.

In reviewing the current approach to radiation risk assessment, the intention of this section is to focus on the relation between the linear, no-threshold model and the present status of empirical knowledge about the health effects of exposure to low-level radiation. The following subsections discuss kinds of radiation injury and the limitations of human studies and then recount the history of the adoption of the linear, no-threshold model; a more detailed history, including discussion of the scientific debates the model's widespread application has occasioned, appears in Appendix K.

Kinds of Radiation Injury

There are two distinct types of radiation injury—*acute radiation injury* and *late radiation injury*. Acute radiation injury, also called prompt injury, occurs in response to large doses of radiation delivered over relatively short periods of time. Acute injuries include erythema (skin reddening), epilation (hair loss), nausea, diarrhea, sterility, organ atrophy, tissue fibrosis, and even death. Some acute injuries may not appear symptomatically for several months; also, some may be irreversible. Acute injuries are said to be *deterministic* (*nonstochastic*) because higher doses lead to more severe injuries.

Late radiation injuries are limited to cancer and hereditary effects. These effects occur at lower doses than those that cause acute radiation injury. Furthermore, the dose may be spread over a longer period of time. Late radiation injuries are often assumed to be *nondeterministic* (*stochastic*) in nature, with a probability, but not severity, that depends on the dose. This assumption implies a model of radiation injury in which the likelihood of long-term radiation injury increases with dose. As noted earlier, this model is unproved at low levels of radiation exposure.

Human Study Limitations

Most of the human data related to long-term effects of radiation exposure have been obtained from epidemiological studies, including those of survivors of the atomic explosions in Hiroshima and Nagasaki. These Japanese survivors are by far the largest and most closely followed of all populations exposed to ionizing radiation. Many uncertainities remain, however, about the universal applicability of the results of the Japanese studies, as is the case with all human epidemiological studies. For example, Japanese survivors had been exposed to a single burst of mixed neutrons and gamma rays; their observed health effects cannot be directly applied or generalized to other groups exposed to different

types of radiation under different conditions, including protracted exposures to much lower levels of radiation. In other radiation studies, populations are frequently composed of individuals who are being treated for various diseases or who are exposed for diagnostic purposes because of suspected illnesses, including those later identified as possibly radiation induced. Dose estimates for exposed individuals in such studies may have to be reconstructed or inferred, often with considerable uncertainty.

Although efforts are often made to compare injury in an irradiated population with that in a comparable control group, it usually is impossible to define a control population that is identical with the study group in all aspects except radiation exposure. Confounding factors frequently are simply ignored because they cannot be verified or quantified. In addition, because radiation effects such as cancer and hereditary injury are not different in expression from those due to "natural causes," studies must focus on increases in incidence and mortality rather than on the mere presence of disease in the exposed population. This difficulty in distinguishing radiation effects from natural causes introduces considerable uncertainty about the extent of health effects in populations exposed to low levels of radiation. In those studies in which health effects are suspected, the occurrence of no effect, or even a beneficial health effect, is within the range of statistical uncertainty (see, e.g., UNSCEAR, 1994).

Models of Radiation Injury

For the first decade or so following the discovery of x-rays in 1895 and radioactivity in 1896, many physicists and physicians experimented with ionizing radiation without concern for possible health effects. Soon, however, they identified effects such as skin burns, hair loss, and ulcerating sores, some of which eventually became skin cancers. Although a few radiation pioneers called for protective measures against radiation, not until the 1920s did physicians and professional organizations, primarily medical societies, acknowledge the need for control strategies and exposure limits for ionizing radiation.

The Tolerance Dose, Threshold Model

In 1925 the concept of the *tolerance dose* was introduced as an upper limit for the exposure of workers to radiation. This concept was based on the premise of a threshold dose, that is, a level of exposure below which ill effects do not occur in exposed persons. The tolerance dose model of radiation injury, with its implied threshold below which adverse effects of radiation exposure do not occur, was the preferred model of radiation injury until after World War II. For many years guidelines for radiation protection, as promulgated by advisory councils such as the ICRP, NCRP, and their predecessors, were based on the tolerance-dose, threshold model of radiation-induced injury.

Introduction of the Linear, No-Threshold Model

In the 1950s, during a period of new concerns about low-dose radiation from peacetime nuclear industries and from worldwide nuclear test fallout, a new model of radiation-induced injury began to be used for the purpose of establishing guidelines for radiation protection. This model assumed that late effects of radiation exposure (late radiation injuries, namely, cancer and hereditary effects) might increase linearly with increasing dose of radiation, and that a threshold dose might not exist below which late effects do not occur. This new model—called the linear, no-threshold model[1] of radiation risk—assumed that the risk of late radiation injuries at low doses can be estimated by linear extrapolation from effects at high doses.

Initially, this model did not dismiss the idea of a threshold dose. Instead, it included that possibility in the implication that the true risk of adverse health effects in the low-dose region lies somewhere along a range between zero and an upper limit defined by linear extrapolation. Over the years, however, the concept of a range of risk values from zero to an extrapolated upper limit has been largely forgotten. Instead, the extrapolated upper limit has assumed prominence as a quantified measure of health risk related to low-level radiation exposure.

Numerous studies of large populations of humans, however, have failed to either demonstrate or refute with statistical significance any adverse health effects related to low-level radiation exposure. Despite this limitation, the linear, no-threshold model has become widely adopted for estimating radiation risk and for quantifying the number of potentially injured persons in a population exposed to ionizing radiation. The basis for this application appears to lie largely in a conservative approach to risk assessment that has been taken to compensate for a lack of reliable data in the relevant low-dose range (NCRP, 1993). Further discussion of the evolution of a linear, no-threshold model can be found in Appendix K.

Summary Observations

The contemporary practice of radiation protection is based on application of the linear, no-threshold model to estimate long-term risks to human health from exposure to low levels of ionizing radiation. This model is currently accepted by various advisory groups including those concerned with the BEIR committees, United Nations Scientific Committee on the Effects of Atomic Radiation, NCRP, and ICRP. It is often coupled with a concept that calls for maintenance of radiation exposures at as low as reasonably achievable levels. The committee assumes that this model is likely to remain as the underlying philosophy for the practice of radiation protection (see, e.g., UNSCEAR, 1962, 1964; ICRP, 1966). As a

[1] Linear, no-threshold models are used for all toxic environmental exposures, not just for radiation. These issues are not unique to radiation or to its use in medicine.

conservative and mathematically simple hypothesis, the linear, no-threshold model provides an upper limit of risk useful for setting protection standards. As a model of risk at low doses, however, it has not been verified by human epidemiological data.

Acceptance of this model has discouraged efforts to establish minimum levels of radiation exposure that can be classed either as "below regulatory concern" or as of "negligible individual risk levels," that is, levels that would imply that regulatory control of exposures is unnecessary (NCRP, 1993). Regulatory programs established to control radiation exposures at low levels should be tempered with a sense of practicality. The committee has two concerns: first, that the costs, both financial and administrative, of efforts to achieve increasingly lower limits of human exposure may compromise useful applications of ionizing radiation and, second, that this situation risks depriving the public of the medical and societal benefits of this medical source. A balance should be attained that reflects not only safe delivery of health care, but also a reasonable level of efficiency and cost-effectiveness in the regulatory process.

RISKS OF IONIZING RADIATION IN MEDICAL TREATMENT

Risk of Unintended Exposures in Radiation Medicine

The preceding section has addressed the issue of risk from the standpoint of how models quantify the harm, if any, caused to humans who are exposed, under any circumstances, to low-dose radiation. This section addresses risk from a different standpoint: When patients are intentionally exposed to ionizing radiation for medical purposes, do they suffer unintentional exposures as a result of error or accident?

No medical intervention, whether diagnostic or therapeutic, comes without risk. Acceptance of medical uncertainty is properly left to the discretion of patients in consultation with their doctors. Some risks, such as those relating to radiation overexposure, underexposure, or exposure of the wrong body part, can be minimized. Training and quality management programs may help to reduce these problems.

Risk in the area of radiation medicine has several dimensions that are less common in other areas of medicine (although not nonexistent). First, there may be risks from overexposure that do not cause immediate injury. For example, the causal connection, if any, may be difficult or impossible to verify for a malignancy that surfaces several years after an inappropriate exposure. Second, the risks associated with the medical use of ionizing radiation extend beyond the patient and can affect health care workers and the public.

In amplifying these and other aspects of the risks that attend medical uses of ionizing radiation, the discussion below addresses the following series of topics:

human error and unintended events; rates of misadministration in radiation medicine; misadministrations and adverse events in other medical modalities; inappropriate and unnecessary care; and efforts that reduce misadministrations and inappropriate care.

Human Error and Unintended Events

Errors occur throughout health care: A pharmacist fills a prescription with the wrong medicine; an x-ray technician takes a film of the wrong leg; a surgeon replaces the wrong hip. The advent of complex medical technology has increased the opportunity for error even as it has increased the opportunity for effecting cures. Injuries within the health care context, including those resulting from human error, are referred to as "iatrogenic."

A landmark Harvard Medical Practice study reported that nearly 4 percent of patients hospitalized in New York in 1982 suffered an iatrogenic injury that resulted in a prolonged hospital stay or measurable disability (Brennan et al., 1991; Leape et al., 1991). The Harvard researchers conducted random samples of both acute care hospitals and patients, identifying some 1,133 adverse events from a total of 30,195 medical records reviewed. The investigators estimated that, of 2.7 million patients discharged from New York hospitals that year, 98,609 suffered an adverse event, for a rate of 3.7 percent of all hospital discharges. Based on the New York rate, the researchers estimated that in the United States more than 1.3 million people are injured annually by treatments intended to help them.

By educating health care workers, and by circumscribing their actions, human error may be minimized. However, some number of mistakes will always, unavoidably, be made, and no amount of training or double-checking can erase that fact. Recent incidents at the Dana-Farber Institute and at the University of Chicago Hospital are cases in point. Both institutions enjoy strong reputations and have quality assurance programs in place; yet, chemotherapy overdoses escaped notice in both systems, killing two patients and leaving a third permanently disabled. Although well-crafted and well-implemented regulatory programs can prevent most safety problems, they cannot completely eliminate human error.

Rates of Misadministration

This report refers to errors and unintended events that occur in the course of administering ionizing radiation in medicine as "adverse events." "Misadministrations" and "reportable events" refer to adverse events involving NRC-regulated byproduct material and are defined at 10 CFR Part 35 (see Appendix D). One task of the committee was to determine how often adverse events occur in the use of ionizing radiation in medicine.

Misadministrations in Byproduct-Related Ionizing Radiation in Medicine

In 1992, NRC data showed 7 diagnostic and 29 therapeutic misadministrations for the 2,228 licensees of the NRC. In that same year, the Agreement States reported 7 diagnostic misadministrations and 10 therapeutic "reportable events" for their 4,944 licensees. Combining the NRC and Agreement State data yields a total, for 1992, of the following numbers of misadministrations or reportable events for 7,172 licensees:

- 38 in therapeutic radiation oncology (teletherapy and brachytherapy);
- 1 in therapeutic nuclear medicine; and
- 14 in diagnostic nuclear medicine.

Even if it is assumed that the numbers are underreported by a factor of 10, owing to confusion as to what is specifically reportable or to intentional non-filing, this level of misadministration is remarkably low.

These figures can be used in conjunction with the total number of administrations in each category to estimate overall error rates. In 1992, about 11 million radiopharmaceutical administrations were given to patients in the United States; approximately 3.5 million of these were provided in NRC-regulated states. Using NRC data on misadministrations for diagnostic procedures (which are higher than those for the Agreement States), these numbers translate to an estimated diagnostic misadministration rate of 0.0002 percent (7 divided by 3.5 million) or about 2 per million administrations (not patients). If data from Agreement States and NRC-regulated states are combined, the estimate of diagnostic misadministrations becomes 0.00012 percent (14 divided by 11,000,000), or about 1.3 per million.[2,3]

[2] The United States Pharmacopoeia (USP) runs a voluntary program within which users of radiopharmaceuticals report problems encountered in the administration of the drugs. Over a two-year period, from October 1, 1993, to September 30, 1995, only 42 voluntary reports were submitted. These "problems" are not misadministrations, but they do include incidents of incorrect biodistribution and other failures inherent in the patient reaction to the drug. Other USP problem reporting programs estimate that voluntarily submitted reports represent 10 percent of actual problems. Reports dealing with radiopharmaceuticals may represent an even higher percentage of actual problems, as physicians involved in the use of radiopharmaceuticals may be even more conscious of safety and adverse events. In any case, the tiny number of reported problems illustrates the low rate of adverse events associated with radiopharmaceuticals.

[3] (ECRI) data reviewed by the committee showed an occurrence of only 168 total adverse events over a three-year period. These data are rough; there is no indication of the number of at-risk administrations, nor is the completeness of reporting defined. Nonetheless, the denominator must be huge. Additionally, of the total 168 events, only 43 caused actual injury.

In the area of therapeutic radiation oncology, administrations in the United States in 1992 were estimated to be associated with treatments for a total of 545,600 patients (as cited by Pollycove, 1993). Of these, 100,600 had byproduct teletherapy and 30,000 brachytherapy. The remaining 415,000 patients were treated with linear accelerator radiation therapy. Thus, the NRC regulatory apparatus is directed at misadministrations involving only about 25 percent of the total radiation therapy patients treated, and only about 0.026 percent of the total of all medication administrations in the United States per year (12 million out of 3.75 billion hospital medication administrations).

Patients receiving radiation therapy routinely receive multiple treatments. For purposes of calculating misadministration or error rates, the reasonable, but conservative, estimates of 20 treatments per teletherapy patient and 2 treatments per brachytherapy patient are used. This yields an annual administration rate of approximately 2 million. Using this figure, one can estimate the byproduct therapy misadministration rate at 0.002 percent (38 divided by 2,072,000, or about 2 per 100,000 administrations).

NRC-regulated states gave about one-third of the treatments. For these states, the estimated misadministration rate for byproduct therapy is 0.004 percent (21 divided by 690,667).

Nevertheless, lacking better data, the committee concluded that approximate rates of byproduct-related misadministrations for 1992 could be said to be:

- for diagnostic misadministrations (Agreement States and NRC-regulated states combined), 0.00012 percent of all such administrations;
- for diagnostic misadministrations (NRC-regulated states only), 0.0002 percent;
- for therapeutic misadministrations (Agreement States and NRC-regulated states combined), 0.002 percent; and
- for therapeutic misadministrations (NRC-regulated states only), 0.004 percent.

All these figures must be regarded as very rough approximations, for several reasons. No information is at hand on the degree of undercounting; the counts themselves are necessarily subject to statistical variation (the standard error of each is roughly the square root of the count); and the denominators are very crude estimates.[4]

[4] It should be noted that the NRC-regulated states have been reporting misadministrations, pursuant to the QM rule (10 CFR 35.32) since January 1992. The Agreement States have only been required to do so since January 1995. Other than this fact, the committee has no explanation for the apparent discrepancy in these rates.

Gaps in Data Collection

Only 10 percent of ionizing radiation used in medicine is subject to the NRC and Agreement State regulatory system. The remaining 90 percent is not federally regulated; in some instances, it is not state regulated either. Because no federal requirement exists for data collection pertaining to non-byproduct radiation sources (other than the Food and Drug Administration (FDA) reporting requirements concerning death, serious injury, or equipment malfunction), realistic, accurate data on the incidence and type of problems associated with non-byproduct radiation medicine remain elusive.

The lack of data is a continuation of a problem noted by the NRC's Office of Policy and Planning in 1993 in its *Task Force Report on Medical Radiation Protection*. The report stated that sufficient data are not available to assess the level of protection for all sources of medical radiation. Although the report noted that acquisition of selected performance data could provide insights needed to consider appropriate regulatory changes, it concluded that "reliable data to assess risk and program effectiveness will be difficult to acquire, especially for non-byproduct sources of radiation" (NRC, 1993, p. 4).

The General Accounting Office (GAO) has also considered the issue of inadequate data (GAO, 1993) and offered two recommendations. First, it advised the NRC to establish common performance indicators to obtain comparable data from all users of byproducts in radiation medicine practice, including both facilities regulated by the NRC and those regulated by Agreement States. The GAO believed that such information would facilitate an evaluation of the effectiveness of the NRC's program and those of the Agreement States. Second, the GAO recommended that the NRC establish specific criteria and procedures for suspending or revoking an Agreement State's program.

The GAO report asserted that the NRC lacked both good criteria and data by which to evaluate the effectiveness of its radioactive materials programs, especially with respect to adequate protection of the public from radiation in either Agreement States or NRC-regulated states (GAO, 1993). It emphasized the need for a common set of performance indicators to evaluate Agreement State and NRC licensees and the need for all users to be required to collect and report information using the same definitions, procedures, and criteria.

Comment

As a general proposition, the committee subscribes to the view that performance indicators can serve the health care industry. Many areas of health care other than radiation medicine deserve equal attention, as suggested by the data cited below on adverse effects of medications in general. With regard to NRC data collection, the committee cautions that efforts directed at radiation medicine

should be justified on the basis of cost and benefit, with both risks of harm to patients and expenditures entailed taken into account.

Today some data are collected on poor performance and adverse events. For example, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has a performance standard that requires intensive assessment when hospital performance varies from recognized standards. The JCAHO specifies confirmed transfusion reactions and significant adverse drug reactions as cause for further assessment, but it does not specifically require hospitals to report medication errors except in accord with the hospital's written procedures (JCAHO, 1995). As another case in point, the medical centers of the Department of Veterans Affairs are required to report and track medication errors. Generally, however, this type of reporting to a central authority does not appear to be practiced in the private sector.

In comparison, where radiation medicine is regulated by the NRC, either directly or through administration of NRC standards by the Agreement States, *all* administrations of radioactive materials must be documented and those that are classified as misadministrations must be reported. In 1992, the volume of services amounted to approximately 11 million NRC-regulated unsealed source radionuclide administrations in nuclear medicine and 130,600 NRC-regulated (brachytherapy and teletherapy) radiation therapy patients. Some members of the nuclear medicine and radiation therapy communities question whether the putative benefits of this level of regulatory oversight and reporting are commensurate with the costs (see Chapter 3), believing that relaxation of this recording and reporting system would not increase the risk of patient injury.

Conclusion

The committee was able to make rough approximations of the rate of misadministrations for medical procedures involving byproduct material. Because of the lack of data, it could not estimate rates for all ionizing radiation used in medicine.

Misadministrations and Adverse Events in Other Medical Modalities

The NRC had asked the Institute of Medicine to compare the errors in use of byproduct materials and the consequences of those errors with errors occurring in other medical interventions. Adverse events in administration of medications, including chemotherapy, blood transfusions, and surgical interventions, were specifically requested for this comparison. In statistical, clinical, and epidemiological terms, comparisons of the risks inherent in very different health care interventions can be problematic. However, the committee judged that such information

would set a useful broader context within which to consider the NRC's regulatory process better.

Medications

Hospitals in the United States provide more than $5 billion worth of prescription drugs and drug products per year (Manesse, 1990). In addition, more than 1.5 billion prescriptions are filled each year in outpatient pharmacies, and additional prescriptions are delivered in outpatient medical facilities, including nursing homes and medical clinics. Although American consumers have greatly benefited from prescription drugs, these medications carry both predictable and unpredictable risks. In addition to known side effects and drug interactions, adverse drugs events (ADEs, defined as an injury resulting from medical intervention) can occur because of medication administration errors.

The numbers of ADEs were researched for comparison with byproduct radioactive materials misadministrations. No comprehensive, consistent, reliable, valid, and accurate accounting of ADEs or drug misadventures is available in the United States (Allan and Barker, 1990). Drug misadventures overall have an elusive denominator and a moving numerator because no one agency or reporting mechanism is standard to all hospitals, outpatient facilities, pharmacies, and nursing homes. Manesse (1989) has suggested that 535 ADEs occur each year, or perhaps 1 per 1,000 prescriptions.

Although the JCAHO requires that hospitals have an ongoing drug surveillance program designed to monitor adverse drug events, mandatory reporting to the FDA is required only for investigational drugs and blood products. The FDA's Adverse Drug Reaction Voluntary Reporting Program collects information on adverse drug reactions from pharmaceutical companies and from physicians, pharmacists, other health care personnel, and patients. In 1987, these groups filed 50,000 adverse drug incident reports with the FDA; of these, 12,000 deaths were attributed to adverse drug reactions, and 15,000 cases required hospitalization (Perry and Knapp, 1987). Adverse drug events may be markedly underreported for hospitalized patients (Classen et al., 1991).

In a recent prospective cohort study, Bates et al. (1993) reported the incidence of ADEs and potential ADEs in 4,031 adult patients admitted to nonobstetrical units of two tertiary care hospitals in Boston from February through July 1993. A total of 247 ADEs and 194 potential ADEs were identified, with extrapolated event rates of 6.5 percent ADEs and 5.5 percent potential ADEs per 100 admissions. Of these ADEs, 1 percent were fatal; 12 percent, life threatening; 30 percent, serious; and 57 percent, significant. Chemotherapy ADEs are generally grouped in with other medications in ADE statistics. In the Harvard Medical Practice Study II, ADEs accounted for 19.4 of the total number of disabling adverse events (Leape et al., 1991).

The Health Care Financing Administration has used error rates determined by direct observation as an indicator of quality for long-term care facilities, with a limit of 5 percent medication error rate regarded as acceptable. A 1988 study indicated that more than 4,000 of the nation's 15,000 nursing homes that participate in the Medicare and Medicaid programs fail to follow physician's orders in administering medications (Anonymous, 1989). Outpatient prescription error rates have been measured at 3.4, 4.2, 5.2, and 12.4 percent (Guernsey et al., 1983; Allan and Barker, 1990).

Anesthesia

Exact data regarding untoward risks of anesthesia are also difficult to quantify. Many confounding variables may interact with such an estimate, including surgical complications, co-morbidity factors, or other patient variables. The medical literature, however, cites certain estimates for anesthesia risks. According to an ECRI technology assessment, more than 2,000 healthy Americans die each year during general anesthesia; an estimated 50 percent of these deaths are preventable (Anonymous, 1985). Derrington and Smith (1987) estimate the mortality rate from the use of anesthesia at 1:5,000 to 1:10,000 patients/ procedures.

Blood Transfusions

More than 12 million units of red blood cells, 5 million units of platelets, and 2 million units of plasma are administered to patients in the United States each year. Adverse reactions are estimated to be as high as 20 percent (Surgenor et al., 1990). Hemolytic blood transfusion reactions occur as often as 1 in 7,000 red blood cell transfusions and carry a mortality rate of 10 percent (Welborn and Hersch, 1991).

Since 1975, fatal errors involving blood transfusions, collection of blood, and plasmapheresis (a procedure by which blood is withdrawn from the donor, the plasma and red blood cells are separated, and the red blood cells are returned to the donor) must be reported to the Center for Biologics Evaluation and Research of the FDA. From 1976 through 1985, a total of 355 fatalities associated with blood transfusions and plasmapheresis were reported; 99 were excluded from further review because they were deemed unrelated to the transfusion itself (Sazama, 1990). Of the 256 analyzed transfusion deaths, 51 percent resulted from acute hemolysis due to transfusion of ABO-incompatible blood products. The remaining causes of transfusion deaths were attributed to pulmonary injury (15 percent), bacterial contamination of the blood product (10 percent), delayed hemolysis (10 percent), damaged product (3 percent), and graft-versus-host disease (0.4 percent).

In December 1989, New York State's health department began mandatory reporting of blood transfusion incidents, accidents, and errors. Linden et al. (1992) reported on the number of these incidents received by the health department from January 1, 1990, through October 31, 1991, and found a total of 104 significant transfusion errors, of which 54 (52 percent) involved the transfusion of incompatible red cells. There were three reported fatal errors (2 per million red cell transfusions).

Comparison of Risks in the Use of Ionizing Radiation in Medicine with Those in Other Medical Modalities

The data reviewed above suggest that the rates of errors in other areas of medicine may exceed those of radiation medicine as reported. Readers are cautioned, however, that no comprehensive raw data are available to make exact comparisons.

In 1993, in a memorandum to NRC's John Glenn, Myron Pollycove, M.D., of the NRC prepared a comparison of the relative risks of radiation therapy, surgery general anesthesia, and chemotherapy (Pollycove, 1993). Pollycove concluded that the actual mortality rates for these health care interventions for five selected cancers far exceeded the mortality from radiation therapy misadministrations. Left untreated, the mortality for these various cancers is much higher than the treatment mortalities, a comparison that does underline the need to weigh the threats of disease against the risks associated with therapy that uses ionizing radiation. Furthermore, these comparisons do relate to quite incommensurate types of adverse events and types of hazards.

In a presentation to this committee, Dr. E. Gail de Planque, NRC Commissioner,[5] observed that the death rates for cancer patients receiving surgery range from 1 to 23 percent, depending on the type of cancer and surgery involved. The risk of dying from chemotherapy is about 1 percent, and anesthesia carries a mortality risk of about 0.1 percent. Of greatest import for this comparison, Dr. de Planque cited a risk of death from correctly administered radiation therapy from byproduct materials at 1 percent, whereas the *additional* risk from misadministration of byproduct materials is only 0.0006 percent. She concluded that "even if all misadministrations were successfully eliminated—so that, as an incoming cancer patient about to undergo radiation therapy, I could be positively assured that my therapy would be properly administered—my risk of death due to the procedure itself would remain essentially unchanged, or about 1%" (de Planque, 1994).[6]

[5] Dr. E. Gail de Planque's term as Commissioner expired in June 1995.

[6] Dr. de Planque's calculations are based on NRC data, which calculate that therapeutic misadministrations of byproduct material occur at a rate of 40 per 100,000 administrations. Of those 40 misadministrations, 30 will result in significant side effects, or morbidity, and 0.6 will result in death. Dr. de Planque also notes that, unless the misadministration results in a particularly high dose, it may be difficult to connect the misadministration with subsequent morbidity or mortality.

This lower rate of adverse events in radiation medicine may be attributable to several things. First, technologies involved in radiation diagnosis and therapy have been advancing rapidly since World War II, and their safety has appreciably improved. Second, the group of health care workers that deal with radiation is small, highly trained, and very aware of the potential dangers. They tend to be particularly careful. Third, the existence of strict regulations early on in the development of the science created an atmosphere in which a high degree of attention is paid to safety in the use of ionizing radiation. The committee recognizes the contribution to safety that NRC regulations have made in the past. However, as discussed later in this report, it believes that this standard of safety can now be maintained through improving technology, professional guidelines, training requirements, and institutional quality assurance programs.

In summary, the comparison of relative risks of misadministrations in by-product radiation medicine to error rates and untoward events in other medical practice settings, as well as the comparison of disease and death rates with the risks of the therapeutic administration itself, help to some extent to place ionizing radiation use in a broader context. Despite the unavoidably tenuous nature of the comparisons, the information raised the question of whether adverse events in radiation medicine are sufficiently widespread or serious to warrant the current burdens of regulation now directed at the field.

Inappropriate and Unnecessary Care

In addition to the problem of adverse events and human error, issues of medical services provided when they are not needed (or may even be contraindicated) arise. Certain surgical procedures provide a dramatic illustration of the problem. In the late 1980s, researchers at the RAND Corporation worked with expert panels of physicians to develop "appropriateness indicators" for several major procedures and health services, including coronary artery bypass graft (CABG). Using those criteria, the researchers were then able to derive a rough estimate of the percentage of patients who underwent inappropriate surgery and died as a result (Winslow et al., 1988a, 1988b). Of 386 cases studied, 56 percent of the surgeries were deemed appropriate, 30 percent equivocal, and 14 percent inappropriate. If one were to assume that the risk-adjusted mortality rate for CABG is 2.45 percent and that 200,000 procedures are performed annually, then (all other things equal) nearly 690 deaths would occur each year solely from inappropriate CABGs performed ($686 = 200{,}000 \times 0.14 \times 0.0245$).

The committee sought similar information from the field of radiation medicine. Few, if any, studies appear to have been done in this area, however, and no

comparable figures on mortality or morbidity from the demonstrably inappropriate or unnecessary use of ionizing radiation are available.

Efforts That Reduce Adverse Events and Inappropriate Care

Even when the error rate is low, unfortunate incidents undermine trust in the health care system and can have permanent repercussions for a patient's health and well-being. The average consumer becomes more aware of the potential for error and the serious ramifications that can occur, regardless of whether the practitioner is fully competent or inadvertently negligent.

In instances of negligence the patient has recourse through the medicolegal system. Electing this course of action does not diminish the negative consequences of the incident itself. Pursuing such actions, however, may decrease the future risk of harm (and eventually raise health care costs through defensive medicine practices). The net impact is difficult to measure.

A key factor to protecting the patient and the public from unnecessary or excessive exposure is the training of professionals who deliver quality nuclear medicine and radiotherapy services. Although a thorough analysis of this area is beyond the scope of the present study, the committee offers the following views.

The NRC should not regulate the education and training of health care personnel; the education and training of physicians and other health-related professionals (including physicists, dosimetrists, radiopharmacists, technologists, technicians, and nurses) should be regulated by professional organizations and societies and by the states. The system of education and training should, however, have greater uniformity than currently exists.

NRC licensure is currently conferred on (a) physicians who have completed specific training programs in radiology or nuclear medicine, and (b) individuals trained in different areas who have completed a requisite number of training hours for limited NRC licensure for specified usage (often organ-system specific). The committee believes that NRC regulatory licensure is imbalanced in two ways: (1) training requirements are disproportionate to actual radiation injury risks; and (2) therapeutic training is underprescribed while diagnostic training is overprescribed. In connection with that, it needs to be recognized that the risks encountered with diagnostic and therapeutic uses of radiation are distinctly different; these differences should be clearly reflected in differences in training. In addition, safety issues appear to achieve undue primacy in the NRC licensure process, in contrast to issues of clinical efficacy and competence. NRC licensure is a poor substitute for broader and more uniform regulation by the professional societies and the states. Education/training should focus on good clinical care as well as patient and employee safety, and it should not merely be an occasion for instructing providers in how to live with currently established regulations.

In a field as broad as nuclear and radiation medicine, clinicians come with a diverse history of training and education in both diagnostic and therapeutic procedures. Training requirements are set by many social and professional institutions, including specialty associations, hospitals, and state licensing boards. Similarly, an array of various institutions may set requirements for nurses, technicians, and other health professionals who provide services in the area of radiation medicine. Further education/training diversity is engendered when differences among particular health care facilities, local traditions, market conditions, and other factors cause similar health care duties to be performed by different types of practitioners.

Patients undergoing diagnostic and therapeutic procedures must be protected against additional risks associated with practitioner inexperience and lack of expertise, and toward this end, diversity of education/training requirements should be reduced. In fact, non-NRC mechanisms are already in place to standardize physician and health physicist education/training as well as requirements for continuing education. Non-NRC education/training deals with issues relating to both radiation safety and biology as well as clinical competence. The non-NRC mechanisms include specialty and subspecialty board certification, the Accreditation Council on Graduate Medical Education, residency review committees, and specialty society standards. However, if professional organizations and the individual states ultimately replace the NRC's licensure authority, the need for a more uniform system of education and training cannot be allowed to lead to a monopoly for any one group of professional constituents. In addition, any system of education/training also must extend beyond hospitals and into the community, encompassing freestanding clinics, physician offices, and other smaller institutions.

Section Summary

Assessing the risks that attach to medical uses of ionizing radiation can be broadly formulated in two basic questions:

1. What is the risk, in any application of ionizing radiation for medical reasons, that unintended exposure to ionizing radiation will also occur or occur instead?
2. If unintended exposure to ionizing radiation does occur, what is the risk that harmful effects will result?

In this chapter, the first of these questions is addressed in the present section on risk of unintended exposures in radiation medicine. In this section the committee discusses its finding that approximate rates of misadministrations in the application of byproduct-related radiation procedures are extremely low. No comprehensive data are available for exact comparison with rates of adverse

events for application of ionizing radiation other than those to which NRC standards apply (in general, naturally occurring and accelerator-produced radioactive material and state-regulated machine-produced radiation). Although the available data for the entire field of ionizing radiation in medicine are therefore sparse, the data on byproduct-related misadministrations lend support to the view that risks of unintended exposure in radiation compare favorably with what is regarded as unavoidable error and resulting adverse event rates, and quite different areas of medical practice, though such comparisons are at best problematic.

The degree to which NRC regulations may account for the extremely low rates of misadministrations found by the committee cannot be determined, but the committee notes that the information it gathered from interviews and testimony during the course of its study showed no evidence of a higher incidence of adverse events traceable to applications of procedures in ionizing radiation in medicine that are not subject to NRC standards (with the one exception involving fluoroscopy, which was addressed by the FDA; see footnote 8 in Chapter 3).

The second basic question stated above is addressed by means of this chapter's review of the linear, no-threshold model used as a matter of public policy to estimate long-term risks to human health from exposure to low levels of ionizing radiation. The current state of empirical knowledge makes it difficult or impossible, as pointed out in the discussion of adverse events, to verify a causal connection between an unintended exposure during radiation treatment and a malignancy that occurs 20 years later. The same lack of empirical knowledge causes the conservative assumption to be made—and applied in the linear, no-threshold model—that any exposure to ionizing radiation may increase the risk of harmful health effects, no matter how small the exposure. Current inability either to verify or to refute this assumption makes it likely that the linear, no-threshold model will continue to be applied. However, combined with the findings discussed in Chapter 3 as to the costs of regulation to the regulated community, the committee's review of the linear, no-threshold model and rates of misadministration leads the committee to the judgment that the extent and strictness of NRC regulation exceed what is optimal in achieving balance between safety on the one hand and cost-effective medical care delivery on the other.

PUBLIC PERCEPTION OF RADIATION RISK

Legislation and regulation are often crafted in response not to the actual risk but rather to the perception of risk. In the context of radiation, public anxiety has long prompted regulation. Ironically, regulation itself can fuel the public's perception that something is risky or dangerous. Surely, it is thought, if there were no risk, there would be no need for government protection. The following discussion addresses the nature of risk perception; the impact of that perception;

and the need for, and potential pitfalls of, communication concerning the risks of radiation.

Nature of Risk Perception

Several approaches have been developed to explore risk perception. One important approach, called the "psychometric paradigm," classifies hazards in order to understand and predict people's responses to different kinds or levels of risks. It attempts to explain why some hazards engender aversion and others indifference, and why various groups differ in their assessments of risk (Slovic, 1987).

This approach was used to assess the perception that different groups had of the risk of dying associated with 30 specific activities and technologies (Fischoff et al., 1978; Slovic et al., 1979). Members of four distinct groups ranked these items in order of least to greatest risk (see Table 4.1), in which the activities and technologies are ordered according to the level of risk (high to low) of whichever group it is. Substantial similarities and some interesting differences existed between the three groups of lay people. All agreed, for example, that handguns and smoking fell within the four riskiest technologies or activities. The experts' judgment of risk departed considerably from that of the lay people. This is illustrated by the markedly different rankings given to nuclear power by lay persons and by experts. This study illustrates the heterogeneity of risk perception and the pitfalls in assuming a shared view for an entire population.

Attempts have been made to understand why some hazards are rated as more risky than others (Fischoff et al., 1978) (see Figure 4.1). In this research, two very strong factors have been associated with risk: "dread" and the "unknown." The dread factor encompasses uncontrollability, catastrophic potential, potential harm to future generations, inequitability (risk borne by some groups while others benefit), involuntariness, and irreducibility. The unknown factor refers to circumstances in which risk is not observable, manifests a delayed effect, or is undiscovered by science. The higher a hazard rates in these two factors, the higher is its perceived risk.

Within this framework, people perceive the risks of nuclear power and those associated with x-rays quite differently (Fischoff et al., 1978). X-rays, which have been used for generations, directly benefit people who voluntarily subject themselves to diagnosis and have little potential for catastrophic harm; they are, accordingly, felt to have a substantially lower risk. In contrast, nuclear power, which is seen as less voluntary, more catastrophic, less controllable, and newer, is considered very risky.

Perception of Radiation Risk

Although empirical evaluations of perception are available for nuclear power and diagnostic x-rays, they are unavailable for other uses of ionizing

radiation in medicine. Inasmuch as it is reasonable to presume that the common adjective "nuclear," in both nuclear power and nuclear medicine, or the word "radiation" itself, may trigger public concern with respect to risk, this section explores the public perception of radiation and the risks it may pose to health and well-being of patients, health care personnel, and the public.

TABLE 4.1 Ordering of Perceived Risk for 30 Activities and Technologies

	Experts	League of Women Voters	College Students	Active Club Members
Nuclear power	20	1	1	8
Motor vehicles	1	2	5	3
Handguns	4	3	2	1
Smoking	2	4	3	4
Motorcycles	6	5	6	2
Alcoholic beverages	3	6	7	5
General (private) aviation	12	7	15	11
Police work	17	8	8	7
Pesticides	8	9	4	15
Surgery	5	10	11	9
Fire fighting	18	11	10	6
Large construction	13	12	14	13
Hunting	23	13	18	10
Spray cans	26	14	13	23
Mountain climbing	29	15	22	12
Bicycles	15	16	24	14
Commercial aviation	16	17	16	18
Electric power (nonnuclear)	9	18	19	19
Swimming	10	19	30	17
Contraceptives	11	20	9	22
Skiing	30	21	25	16
X-rays	7	22	17	24
High school and college football	27	23	26	21
Railroads	19	24	23	20
Food preservatives	14	25	12	28
Food coloring	21	26	20	30
Power mowers	28	27	28	25
Prescription antibiotics	24	28	21	26
Home appliances	29	22	27	27
Vaccinations	25	30	29	29

Note: The ordering is based on the geometric mean risk ratings within each group. Rank 1 represents the most risky activity or technology.
Source: Slovic, 1987, Table 1, p. 281; reprinted with permission. Copyright 1987 by American Association for the Advancement of Science.

Evidently, people perceive that different sources of radiation exposure pose different levels of possible harm (Kunreuther et al., 1988; Slovic et al., 1991b) (see Table 4.2). For instance, experts recommend that action be taken to reduce

the moderate risk associated with radon, but the public is apathetic toward the problem. Conversely, consumers question the acceptability of food irradiation, while experts dismiss such worries. Perhaps the difference is clearest when it comes to nuclear power. Experts consider this a moderate, but acceptable, risk, whereas the public has serious questions about the safety of nuclear power.

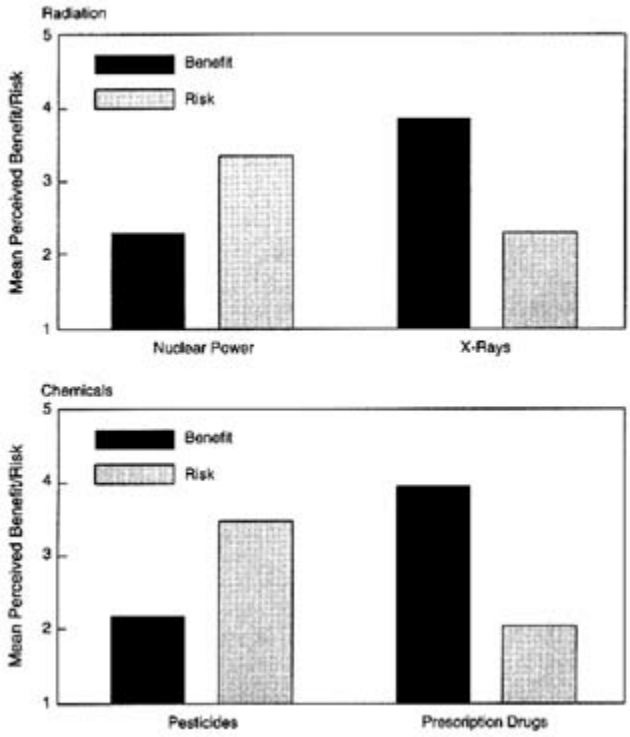

FIGURE 4.1 Mean perceived risk and perceived benefit for medical and nonmedical sources of exposure to radiation and chemicals. Each item was rated on a scale of perceived risk ranging from 1 (very low risk) to 7 (very high risk) and a scale of perceived benefit ranging from 1 (very low benefit) to 7 (very high benefit). Note that medical sources for exposure have more favorable benefit/risk rating than do the nonmedical sources. SOURCE: Slovic, 1993.

The association of radiation, nuclear power, and nuclear waste with catastrophe has a long history (Weart, 1988). The bombings of Hiroshima and Nagasaki are forever a part of the public's collective memory: "Nuclear energy was conceived in secrecy, born in war, and first revealed to the world in horror. No matter how much proponents try to separate the peaceful from the weapons atom, the connection is firmly embedded in the minds of the public" (Smith, 1988). In addition to immediate destruction, public fear relates to contamination,

whereby radiation affects the landscape, body tissues, and the genetic makeup of future generations (Erickson, 1990, 1991).

TABLE 4.2 Summary of Perception and Acceptance of Risks from Diverse Sources of Radiation Exposure

	Perceived Risk	
	Technical Experts	Public
Nuclear power/nuclear waste	Moderate risk Acceptable	Extreme risk Unacceptable
X-rays	Low/moderate risk Acceptable	Very low risk Acceptable
Radon	Moderate risk Needs action	Very low risk Apathy
Nuclear weapons	Moderate to extreme risk Tolerance	Extreme risk Tolerance
Food irradiation	Low risk Acceptable	Moderate to high risk Acceptability questioned
Electric and magnetic fields	Low risk	Significant concerns beginning to develop
	Acceptable	Acceptability questioned

SOURCE: Slovic, 1990, Table 2, p. 79; reprinted with permission. Copyright 1990 by National Council on Radiation Protection and Measurements.

In contrast is the public's lack of concern regarding radon. Although some experts view radon as a moderate risk requiring action (Bord and O'Connor, 1990), the public, influenced by radon's natural origin, its occurrence in a familiar setting, and the absence of someone to blame, sees radon as extremely low risk. Similarly, experts rate nuclear power as a lower risk than medical x-rays, whereas lay persons think just the opposite (see Table 4.1).

Impact of Perceptions

When people perceive that something is hazardous or poses threats to life, health, or well-being, they want that risk reduced and they are willing to employ regulation to do so. Accusations by experts that public reactions are "irrational" or "phobic" notwithstanding, perceptions are real and must be dealt with. Public assessment of risks has ripple effects that can result in substantial social, political, and economic impact. The accident at Three Mile Island, for instance, not only affected that specific nuclear plant but also had enormous implications for the nuclear industry and for society; these included stricter regulation, increased costs of reactor construction and operation, fewer reactors worldwide, greater public opposition to nuclear power, and reliance on more expensive energy sources (Evans and Hope, 1984; Heising and George, 1986).

A theory as to how various factors in society "amplify risks" and produce ripple effects has been presented by Kasperson et al. (1988). The long-range impact of an event depends upon its "signal value," which reflects new information about the likelihood of similar future events. This signal value relates to the context in which the event takes place. For example, a train accident with major loss of life may produce little social disturbance if it occurs within a familiar system. In contrast, a smaller accident within an unfamiliar system, such as a brachytherapy misadministration, may have immense social impact if it is viewed as a harbinger of future major mishaps. Society understandably reacts negatively to poorly understood and seemingly catastrophic events.

Risk Communication and Trust

The variety of risk perceptions and the heterogeneity of assessment among experts and lay persons make risk communication extremely important. Despite the substantial difficulty involved, the public must be better informed about risks so that they can put them into perspective, facilitate decisionmaking, and diffuse unnecessary anxiety. However, even well-thought-out approaches to risk communication have the potential for achieving just the opposite result; namely, they can enhance public distrust. In fact, the very discussion of potential risk might be perceived as revealing a real risk.

Several approaches have been used to communicate risk. One such approach has been "risk comparisons" (Wilson, 1979). Such comparisons may be more meaningful than the presentation of simple probabilities, especially when these numbers are quite small. Risk comparisons may provide some clarity, especially for persons comfortable with quantitative analysis, but they do not always educate effectively among groups less "numeric" in training or orientation.

The way information is presented is also important in influencing risk perceptions. Subtle changes in the way that risks are "framed" can have a major impact on decisions. This was amply demonstrated in a landmark project in medicine (McNeil et al., 1982). In it, the investigators demonstrated that when individuals are offered the options of surgery or radiation therapy as treatment for lung cancer, the percentage of patients choosing a specific therapy dropped dramatically when success rates were stated in terms of dying rather than surviving.

Indeed, the very discussion of risk can fuel a perception of potential hazards. Even assurances of low risk fail when the public focuses on the word "risk" and not on its minimal ("low") nature. In this sense, regulations first developed to provide safe nuclear energy and then superimposed on the medical use of byproduct material communicate to the public a continuum of hazard. Within that communication, the concept of absolute risk, rather than degree of risk, predominates.

Perceptions also relate strongly to trust. Greater public acceptance of medical, as opposed to industrial, technology grows from a relatively high degree of trust in physicians.[7] The limited effectiveness of risk communication efforts in many circumstances may be attributable to lack of trust. Trust, in fact, may be more fundamental to changing public perception of risk than is clarity of communication.

Trust is a fragile phenomenon. It tends to be created slowly, may be destroyed by a single mishap, and takes a long time to rebuild. This asymmetry is believed to be a mechanism of human psychology (Slovic, 1995).

Trust-destroying events are more visible to the public, and they carry much greater weight than do trust-building events. As a case in point: college students who rated the impact on trust of a series of 45 hypothetical events pertaining to the management of a large nuclear power plant demonstrated this asymmetry dramatically (see Figure 4.2). For example, although on-site inspectors and responsiveness to the first signs of problems inspire some trust, the discovery of poor recordkeeping decreases trust by an even greater percentage.

The importance of an event also relates in part to its rarity. An accident in a nuclear plant affects trust far more than does a large number of accident-free days. Another aspect of the asymmetry principle is the phenomenon whereby trust-destroying news is seen as more credible than good news. For instance, one study demonstrating potential carcinogenicity in animals carries more weight in the public mind than several studies that disprove such an effect (Efron, 1984). Another important psychological tendency is that distrust, once initiated, tends to reinforce and perpetuate future distrust.

The news media also give greater weight to negative than to positive events, thriving, as they do, on trust-destroying news. On March 20, 1991, the *Journal of the American Medical Association* carried two studies, both of which evaluated potential links between radiation exposure and cancer. One study indicated an increased risk in leukemia for white men working at the Oak Ridge National Laboratory. The other suggested no increased risk of cancer in people residing near specific nuclear facilities. The subsequent newspaper coverage focused in far greater detail on the study showing increased risk than on the other article (Koren and Klein, 1991).

Implications for Radiation Medicine

The past 20 years of research into the perception of risk have seen little attention paid to medical uses of radiation, in contrast to multiple studies evaluating the perception of risks associated with nuclear power and waste. Analogous to x-rays, other radiation in medicine is likely to be viewed more

[7] Such trust, however, may be waning in the face of higher costs of medicine, the epidemic of malpractice claims, and the general public decline in deference to authority.

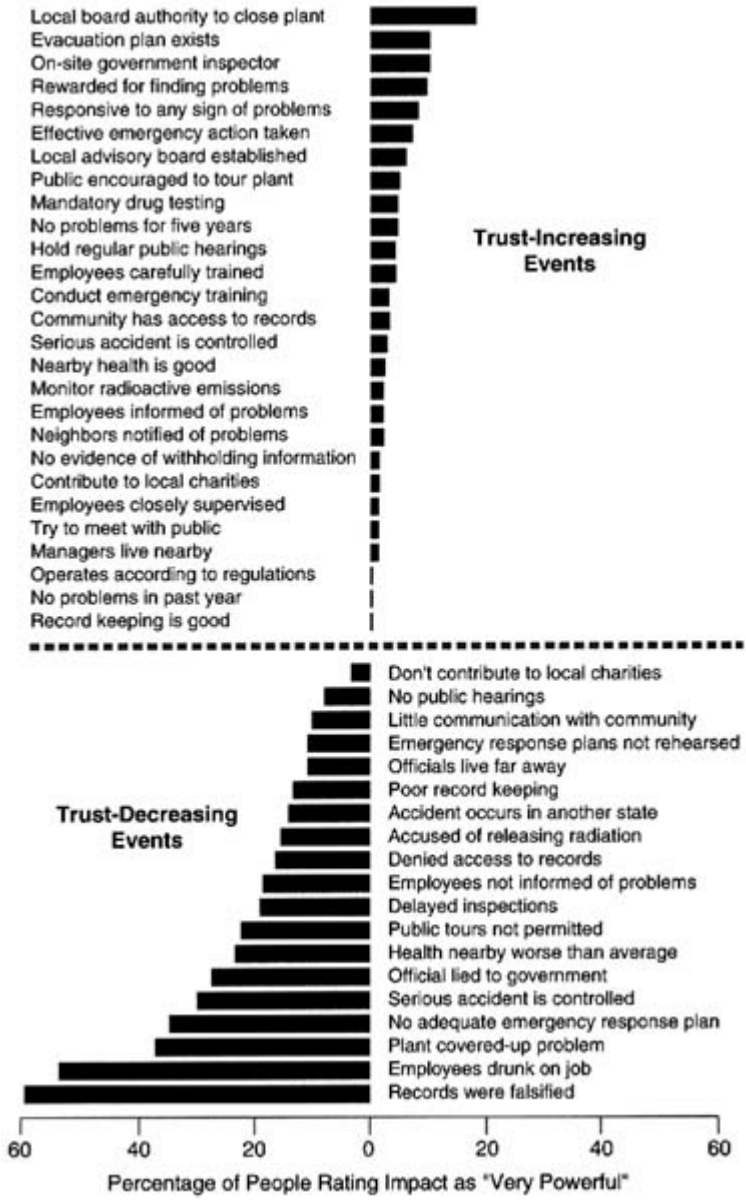

FIGURE 4.2 Differential impact of trust-increasing and trustdecreasing events. NOTE: Only percentages of Category 7 ratings (very powerful impact) are shown here. SOURCE: Slovic, 1993.

favorably than nuclear power because of the perceived benefits associated with medicine and the relatively strong trust in the medical profession. Public perception, however, is not free of anxieties associated with radiation's risk of subsequent cancer. In view of the psychological profiles discussed above, strong public reaction to incidents of overexposure is not surprising. Small incidents can cause major ripple effects, and these in turn may prompt calls for stricter regulation.

Further studies are clearly necessary to understand some of the perceptions of radiation medicine risk. There is a distinct need to develop appropriate strategies for dealing with these perceptions. Effort should be placed on trust-building strategies that ease the "dread" and "unknown" aspects of radiation risk. The major medical benefits of radiation medicine must be emphasized. Furthermore, the perceptual linkages among nuclear power, Three Mile Island, and radiation medicine must be uncoupled.

CHAPTER SUMMARY

This chapter has explored several aspects of the risks involved in the use of ionizing radiation in medicine. Having set out basic concepts necessary to understanding the regulation of these risks, including the linear, no-threshold model currently used by U.S. regulatory agencies, the chapter then goes on to look at what is known about the actual incidence of adverse events in radiation medicine. Although comparisons between misadministrations involving NRC-regulated materials and adverse events in other medical modalities are imperfect, the committee felt that such a broad contextual view helped it in its assessment of the risks arising from use of byproduct materials. Finally, recognizing that regulation is often as much a response to public pressure as it is to scientific opinion, the committee has included a look into what is known about the public's perception of ionizing radiation.

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5

Alternative Regulatory Systems

One of the committee's tasks was to make recommendations on a uniform national approach to the regulation of ionizing radiation in all medical applications; the underlying aim was to promote the benefits of radiation and to improve patient care and outcome. During its deliberations on which form a uniform national approach should take, the committee considered a wide spectrum of alternative regulatory structures. By exploring a full range of options and elucidating the pros and cons of each, the committee sought to identify both strengths and problems within the current system and to focus on the alternative most likely to deliver the greatest net benefit to society.

In this chapter, the committee analyzes and synthesizes all of the information presented in Chapters 2, 3, and 4, and explores a range of options for the regulation of ionizing radiation in medicine. This chapter describes the seven main regulatory structures that the committee considered. It discusses the advantages and disadvantages of each and provides an overall assessment of each, ultimately explaining the rationale behind the preferred alternative. The preferred alternative outlined and discussed in this chapter forms the basis for the recommendations presented in Chapter 6.

On balance, after assessing the existing regulatory system, the committee's impressions of its major problems are:

- the Nuclear Regulatory Commission (NRC) regulates only 10 percent of all ionizing radiation in medicine and that uniform regulation of all ionizing radiation in medicine is desirable in the medical context;

- the NRC's regulatory enforcement strategy is burdensome; the benefits from this process are not commensurate with the burdens imposed;
- the NRC intrudes into the practice of medicine; promulgation of the Quality Management Program and Notification, Reports and Records of Misadministrations, 10 CFR 35.32 and 35.33 respectively, involves the practice of medicine; and,
- the expenditure of resources (funded exclusively by user fees) to reduce adverse events involving byproduct material, extends beyond the point at which the additional dollar spent on regulation achieves an equivalent dollar of benefit to patients or the public.

In considering each of the proposed alternatives, the reader should remember that, in all but the laissez-faire model (Alternative B), the basic structure of federal regulation and responsibility would remain in place. Federal agencies would retain their existing responsibilities for the generation, transport, nonmedical use, and disposal of radionuclides, for the approval of radiopharmaceuticals, and for certification or approval of equipment that generates ionizing radiation. In particular, this means that:

- the NRC and its Agreement States would continue to license the production of byproduct material for radiation-producing devices and radiopharmaceuticals;
- the NRC and its Agreement States would, as relates to nonmedical uses (i.e., industrial, educational, and nonmedical research), continue to license the production and use of byproduct material;
- the Department of Transportation (DOT) would continue to regulate the transport of radioactive materials;
- the Environmental Protection Agency (EPA) would continue to develop guidelines that set occupational and public exposure limits to be implemented by the respective federal agencies;
- the Food and Drug Administration (FDA) would continue to regulate the manufacture and labeling of radiopharmaceuticals and medical devices.
- the FDA would also continue to regulate the mammography program under the Mammography Quality Standards Act (MQSA);
- the Department of Defense (DOD), the Department of Veterans Affairs (VA), and the Public Health Service (PHS) would continue to be responsible, under the regulations of the appropriate agencies, for the safe use of radioactive materials and radiation-producing machines in their hospitals and laboratories; and
- the Health Care Financing Administration (HCFA) would continue to develop reimbursement guidelines for Medicare and Medicaid (as will other federal agencies for other health care purchased from the private sector).

Additionally, under the alternatives where each state has a role in regulating the use of ionizing radiation in medicine, the committee assumes that the Conference of Radiation Control Program Directors (CRCPD) will continue to develop suggested state regulations and to help coordinate state programs. The CRCPD will continue in its role for the nonmedical use of radioactive materials.

SEVEN ALTERNATIVE STRUCTURES

The alternatives discussed below pertain to two parts of the Code of Federal Regulation (CFR)—10 CFR Part 35: Medical Use of Byproduct Material, and Part 20: Standards for Protection Against Radiation. The focus is on those CFR provisions as they affect institutions and individuals involved in the medical and biomedical research use of radiation in medicine.

The committee first discusses the status quo (A1) and a variation upon that situation (A2). It then proceeds to discuss a spectrum of alternatives, varying from a market-based system (B) to a comprehensive and centralized federal system (G). Alternatives C, D, E, and F present a more conventional continuum for addressing regulation. These latter alternatives examine the differences between exclusive state regulation (C), state regulation accompanied by a federal advisory presence (D), state regulation accompanied by limited federal authority (E), and centralization of federal regulation at the federal level (F). In particular, the NRC retains responsibility for licensing the production of byproduct material for use in radiation-producing devices and radiopharmaceuticals. Each alternative is described, followed by a discussion of its pros and cons. The last section of this chapter assesses the alternatives and identifies the one preferred by the majority of the committee.

Alternative A1: Status Quo

Before determining whether an alternative to the existing system should be devised to regulate ionizing radiation in all medical applications, the committee assessed the NRC's current program and considered two possible options for NRC action.

The first possibility is for the NRC to continue operating exactly as it has in the past and does today. In Chapter 4, estimates of the actual rates of misadministrations were presented. In the early stages of regulating ionizing radiation in medicine, NRC regulations may have contributed to the low incidence of misadministrations because they imposed considerable constraints on the users. Such constraints included strict licensing of physicians and institutions and limits on permissible uses of radioactive materials and on the amount of such materials that an institution could possess. If one infers that the current low rate of misadministrations is a direct result of the history of these regulations and the current

regulatory regime, a change in structure may not be justified on the basis of safety.

Pro

For reasons discussed below, the committee found it difficult to see any positive aspects to this alternative. Given the inherently conservative nature of federal agencies, this might be the easiest alternative to realize, inasmuch as no action is required.

Con

The NRC currently regulates only 10 percent of all ionizing radiation in medicine and the committee feels that uniform regulation of all such use is desirable. All in all, the committee believes that the NRC's current system for regulating the use of byproduct material in medicine and for enforcing those regulations should not remain as it is. The committee uncovered several problems with the status quo that need to be addressed and are discussed throughout the report. In particular, the committee found that the NRC's present set of regulations and its approach to enforcement has evolved to the point where it is overly prescriptive rather than performance-based. Actions taken by the NRC against user institutions tend to be disproportionate to the violations, not so much in the magnitude of fines as in its public announcements of citations, and its unrealistic paperwork demands.

Alternative A2: Status Quo Modified

A second possibility requires some minimal change to the current system to deal with these problems. One criticism of the NRC's regulation of the medical use of ionizing radiation is directed specifically at 10 CFR 35.32 (quality management program) and 35.33 (notifications, reports, and records of misadministrations), both of which became effective in 1992. This alternative would either eliminate these two sections of the NRC's regulations or make the sections voluntary by having the NRC announce that it will ease the manner of definition and thus enforcement. The committee believes that less stringent programs enforced by existing professional organizations and societies, such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the American College of Radiology (ACR), and liability law would be sufficient to maintain the low rate of problems reported in Chapter 4.

This new approach is something that the NRC, within its current legislative authority, could implement without delay or public comment. This single change would greatly facilitate bringing NRC regulations into line with the way that health care in general and ionizing radiation in particular (except for byproduct

materials) is regulated. The committee judged that this step toward uniformity would be of real value.

The concepts that are currently reflected in 10 CFR 35.32 and 35.33 could be incorporated into NRC educational programs and enforced by the states or professional societies. This step would greatly assist in reinstating the NRC as a professional leader rather than enforcer. Because there is value in having a thoughtful set of guidelines concerning the use of byproduct materials, the NRC might continue to formulate voluntary guidelines concerning quality management. The NRC might contract with the CRCPD to write these guidelines, or it might adopt the quality management programs set forth by the JCAHO or the ACR.

The reporting requirements in 10 CFR 35.32 and 35.33 could be handled through the FDA, which requires notification of adverse events and medical device failure incidents under the authority of the Food, Drug, and Cosmetic Act. The NRC could strengthen its collaboration with the FDA so that incident reports associated with products would be made available to the NRC. This could provide a continuous assessment of the adverse event rate for byproduct materials used in medicine.

Pro

Adopting Alternative A2 would not require legislative change. It would only require the NRC to exercise discretion by indicating to the regulated community that the agency does not intend to enforce existing regulations in the current manner defined, monitored, and policed. The NRC could possibly promulgate a new regulation that does away with 10 CFR Part 35 entirely, but that step would entail the cost and resources of a formal public comment period. Thus, this alternative is the easiest and fastest way to effect a change in the existing system and to address the concern expressed by the medical community without calling for a sweeping reorganization. However, this alternative does not address the committee's concerns, as discussed below.

This alternative also provides the NRC with an opportunity to make useful changes in its work culture. The NRC would no longer treat minor deviations as serious violations. Emphasis on working with the regulated institutions by answering questions, providing help in meeting regulations, and viewing violations in terms of risk could alter and improve their performance. Thus, this alternative enables the NRC to retain highly trained personnel who can be reassigned to more productive tasks. It would also produce a work environment more responsive to the concerns of the medical community, without sacrificing the radiation safety accomplishments that NRC has achieved over the years.

Con

Adopting this alternative does not address two of the committee's concerns: (1) that ionizing radiation in medicine is not regulated consistently—sources used regularly in the practice of medicine are treated unevenly; and (2) that safety can be maintained at lower cost. The existing, illogical system would remain intact, allowing what might still be fairly intense regulation of reactor byproduct material at the federal level and no comparable federal regulation of the uses of other sources of radioactivity (which add up to a significantly greater percentage of all the uses in radiation medicine). Since World War II and the advent of the use of radiation for peaceful purposes, a regulatory differentiation has existed between byproduct materials, on the one hand, and naturally occurring and accelerator-produced radioactive materials (NARM) and machine-produced radiation, on the other. Numerous congressional committees have examined this issue, but no changes have been effected to eliminate the disproportion. Indeed, the issue arises as to whether NRC regulation is at all necessary, given the fact that the regulation of NARM and machine-produced radiation has, since the early 1900s, been left to the states and to the FDA via the premarket approval process of drugs and devices.

In addition, this slight modification to the status quo with regard to NRC regulation fails to solve the problem of the rising costs of the existing NRC licensing program. As more states become Agreement States, license fees for users in the remaining states keep increasing to meet the NRC's administrative expenses. Nor does it completely alter the increasingly prescriptive NRC regulations and aggressive enforcement that seem inappropriate in the medical context.

Alternative B: Laissez Faire

Available data, as reviewed in Chapter 4, indicate that the quality of practice that utilizes ionizing radiation is relatively good, perhaps excellent, though data on the point are not as strong as desired. Further, this seems to be the case for both the areas regulated by the NRC and the areas of ionizing radiation use outside the NRC's control. In light of this information, the committee considered the proposition that all forms of medical radiation regulation—federal and state—should be eliminated and that responsibilities for radiation safety should be left to medical practice, medical societies, and the marketplace.

A market system pervades the developed world. Individuals retain a wide area in which personal decisionmaking is subject to little or no government intervention. Most choices are left entirely to the consumer, with only a warning of caveat emptor. Even extremely risky personal activities such as skydiving, spelunking, and mountain climbing are generally free of government regulations. Personal choice is valued over the risk of occasional deaths and injuries.

Medical care, in contrast, is usually regulated to some degree. The level of regulation varies by country, by type of health care system, by type of health care

intervention, and any other number of variables. Many activities risky to patients (e.g., anesthesia, surgery, and the prescribing of pharmaceuticals) are subject to minimum or moderate levels of regulation. Others, such as the use of byproduct material in medicine, are subject to far more stringent regulations. Depending on the country, governments may regulate some medical modalities disproportionately in comparison to others, sometimes without considering the relative risks involved.

In keeping with the value placed on personal choice in a free market environment, Alternative B would do away with existing federal and state regulatory controls over the use of all ionizing radiation in medicine, including byproduct material, NARM, and machine-produced radiation. It would encourage the replacement of existing governmental regulation with guidelines developed and implemented by organized medical groups and professional societies. Product approval and the regulation of the sale of source material to users would no longer be a federal responsibility. Neither the NRC nor the FDA would have any role in regulating the medical use of ionizing radiation.

The federal role would encompass only what is necessary to facilitate interstate commerce, namely, transport of hazardous materials. Thus, even under this alternative the DOT would continue to regulate transport of hazardous materials, HCFA would still determine what it would reimburse under Medicare and Medicaid, and agencies that operate medical facilities would still promulgate their internal rules. Under this alternative, states would have a minimal role, which would not extend beyond licensing professionals and facilities. Unsafe uses of ionizing radiation would be subject to such penalties as loss of license and malpractice suits. Additionally, physicians might lose hospital privileges, and hospitals could be subject to loss of accreditation.

Alternative B is predicated on the view that current regulation is excessive for the risks involved in the medical use of radiation. It assumes that patients, medical workers, and members of the general public are not at significant risk and that the necessary degree of protection can be reached through the voluntary and educational activities of professional societies and associations. It would also require abolition of several federal regulations.

Pro

This is the least costly alternative of all those considered by the committee. Because it requires neither federal nor state regulatory funding, taxpayers save money. In effect, it lifts a large administrative burden. The medical profession would assume sole responsibility for medical safety and would be freed from what some perceive as overregulation. Physicians would have the opportunity to be more innovative in patient care. In theory, competition could lower prices, creating greater access for the patient community.

Con

Not everybody is conscientious about radiation protection. Neither does anybody really know the possible long-term consequences of ionizing radiation exposure. The unregulated use of ionizing radiation in medicine may lead to more radiation injuries than occur at present. Without an outside stimulus, such as regulation and enforcement, the health care sector might not invest the time and money necessary to effect voluntary quality management programs. The threat of malpractice litigation might not work to prevent injuries.

Another problem is the inability of patients and consumers to judge the effectiveness of a facility's radiation control program, especially at a time when patients are preparing for diagnosis or treatment. Patients may not understand the potential dangers and benefits of ionizing radiation, and they may lack sufficient information to make informed decisions, although the same is true of the risks of almost all medical procedures. In addition, the public in general is concerned about radiation exposure. Even though public perception of the risk of the use of radiation in medicine is challenged by experts, the public is probably still sufficiently concerned about the release of radiation into the environment that it might oppose completely unregulated use.

Many committee members had little expectation that the marketplace, the malpractice system, and the professional societies could, by themselves, weed out incompetent practitioners and ineffective procedures. Without the role of government in maintaining standards, the committee believed that this approach to regulation would be unacceptable to the majority of Americans.

This extreme deregulation alternative assumes that existing federal and state laws would be amended and regulations revoked. Yet, given that most states already regulate ionizing radiation in medicine to some degree, it seems unlikely that all these states could be convinced to follow the approach outlined in this alternative. Although a trend is developing in the United States toward greater reliance on the marketplace for health care delivery, there is no serious movement toward a true laissez-faire structure. On the federal level as well, it would be difficult to overcome a half-century's tradition of regulation. Finally, limiting this approach to medical uses of ionizing radiation might be unwieldy, as the existing federal regulatory structure for radiation control in industry, research, and consumer products would continue unchanged.

Alternative C: State Control

Alternative C would eliminate NRC control of the medical uses of byproduct material. Instead, it would give regulatory authority over such uses to the states, and it would rely on the states to expand their existing radiation control programs that apply to NARM to include byproduct material as well. Under this alternative, byproduct materials would be regulated in the same way that x-ray

machines, linear accelerators, pharmaceuticals, and other medical devices and materials are currently regulated.

As mentioned at this chapter's outset, federal agencies would still have certain regulatory responsibilities. For instance, the FDA would continue to regulate the safety and efficacy of radiopharmaceuticals and radiation-emitting medical devices, and the DOT would continue to regulate the transportation of byproduct materials. The NRC would still license the manufacture of byproduct materials. Regulatory responsibility for the use of byproduct materials in medicine, however, would pass from federal to state agencies.

Each state could choose from a variety of approaches. For example, one state might choose to regulate stringently through a state agency; another might control medical practice through its licensure of providers; a third might delegate disciplinary authority to professional medical associations; and a fourth might entrust safety to the threat of malpractice suits.

The emphasis on state regulations does not preclude uniformity among the states, given the CRCPD's longtime efforts in devising the *Suggested State Regulations for Control of Radiation (SSRCR)* and their widespread adoption by the vast majority of the states. Although, theoretically, Alternative C allows for one state to embrace a laissez-faire approach while another increases the intensity of existing state radiation regulations, the expectation is that the states with existing programs based on the *SSRCR* would continue their programs and reinforce the movement toward greater uniformity. The majority of states have adopted the *SSRCR*, either in toto or in part.

States have been using the *SSRCR* since 1962. These regulations are written so that, when they are adopted by the states, they do not conflict with existing federal radiation regulations. The CRCPD, in conjunction with several federal agencies, now revises them on an ongoing basis. The primary federal agencies working on the revisions with the states are the NRC and the FDA, but depending on the regulatory subparts being revised, the EPA, the DOT, and the Department of Energy may also be involved. The CRCPD also gets input from standard-setting groups, professional organizations, industry associations, and international organizations. The success of this alternative would be aided by the continued funding of the CRCPD, which is presently supported by the NRC, FDA, and EPA, and by continued cooperation in the updating of the *SSRCR*.

In short, under this alternative, the CRCPD would encourage all 50 states and the U.S. territories presently subject to NRC regulation to adopt the *SSRCR*. Nevertheless, the states would be the sole regulatory structure in place, and each would clearly have the option of not regulating at all.

Pro

Alternative C eliminates the detailed and burdensome regulatory procedures of the NRC on medical practice, and it places regulatory authority and responsibility

squarely within the states. Because almost all states exercise some form of regulation over the use of ionizing radiation in medicine in addition to conducting regulatory programs for all sources of ionizing and nonionizing radiation used in industry and research, this alternative could build on programs already in place and move in the direction of greater uniformity. This should result in less expense at the federal level, without necessarily shifting equivalent costs to the states.

The committee believes that states should strive towards uniformity among themselves, based on the CRCPD's longtime efforts in devising the *SSRCR* and their widespread adoption by most states. Theoretically, therefore, this alternative allows for a state either to embrace a laissez-faire approach or to increase the intensity of its existing state radiation regulations. The main assumption for Alternative C, however, is that all of the states with existing programs would continue and expand their programs based on the *SSRCR* and thus reinforce the movement toward greater uniformity.

Con

The committee, in all its fact-finding, found no real assurance that states want to assume this responsibility. Although the majority of the CRCPD representatives[1] seem to favor assumption of state regulation for all ionizing radiation, no official statement has been made.

In addition, the committee recognizes that not all states currently have strong regulatory programs in place for NARM and machine-produced radiation. Twenty-one states, those that are not currently Agreement States, would have to absorb the additional expense of regulating byproduct material. These states may lack the resources, including qualified personnel, that would enable them to set up their own safety programs. However, these states face higher costs in any case, because under the existing program, the declining base of licensees (as more states become Agreement States) would most likely result in higher fees for the remaining Non-Agreement States.

Furthermore, state legislatures might not appreciate the reasons for NRC regulation of industrial uses of byproduct materials, while expecting the states to assure safety for medical uses of such material. Moreover, some state legislatures might be receptive to strong antiregulatory interest groups and ignore weak consumer

[1] Several CRCPD representatives drafted a paper, "A New Concept for Developing Regulations Relating to the Use of Sources of Radiation," that was presented at the CRCPD's annual meeting in 1995. That paper proposes that a new entity be formed within the CRCPD that would have, as its sole function, the development and promulgation of regulations relating to the use of sources of radiation, thereby delegating to the states regulatory authority over virtually all radioactive materials. The CRCPD appointed a committee to review the feasibility of the report.

groups, leaving patients in those states relatively unprotected from poor or unsafe medical practice in this area.

The lack of leadership at the federal level, under this scenario, would make it more difficult to encourage states to adopt CRCPD guidelines, to provide training of state personnel, and to facilitate state interface with various organized medical professional groups. Because the CRCPD is funded mainly by federal agencies, Alternative C, which eliminates the regulatory authority of those agencies, might also seriously undermine the CRCPD's continued operation. In addition, states might abandon the radiation safety programs already in place without the incentive from a federal agency to continue operating them. Considering the current fiscal crises in many jurisdictions, states might well shift money from such safety programs to meet other social needs. Finally, a patchwork system of regulations might compromise the ability of businesses to participate in interstate commerce.

Public safety in the medical use of ionizing radiation would yet exist in the fact that the NRC would still retain the responsibility of licensing manufacturers (i.e., nuclear power plants and radiopharmaceutical companies) and, consequently, could ensure that byproduct material was withheld from any state that failed to license users and regulate the use and safety of byproduct material.

Alternative D: Federal Guidance

Alternative D modifies Alternative C by identifying a federal agency, other than the NRC, to exercise a leadership role in the radiation safety community. Such a federal agency would assist in developing recommended state laws and regulations for all ionizing radiation in medicine, building on the activities of the CRCPD and the *SSRCR* . It would also provide leadership, act as an information clearinghouse, and distribute resources for training and research. Similar to the MQSA effort that brought together the FDA and professional organizations, the Department of Health and Human Services (DHHS), for example, could work in conjunction with the CRCPD and other professional organizations to enhance the existing *SSRCR* and promote their adoption, thereby encouraging greater regulatory uniformity among the states. Because the majority of states already follow the *SSRCR*, an important DHHS function would be to ensure the continued viability of the CRCPD and to update material in a timely fashion.

Although, under this alternative, states cannot be compelled to accept the voluntary guidelines or *SSRCR*, a variety of forces can greatly influence them to do so. A collaborative effort of the proposed federal agency, the states, the CRCPD, and other professional organizations (not unlike the process utilized in developing the mammography regulations that involved the FDA, the ACR, and other professional organizations) would facilitate an interactive process, allowing an exchange of ideas, so that controversies might be resolved before implementation. Respect for and investment in the process, in contrast to a unilateral

mandate from a federal agency, would develop a keen interest in successful implementation on the part of all participants.

Other reasons exist for states to adopt voluntary guidelines and the *SSRCR*. Professional peer pressure, from the people within each state who are involved in developing the *SSRCR*, would exert substantial influence to make the process work. Consumer groups and the media, seeking to ensure that the citizenry is protected, would also exert pressure. State medical societies would also want regulatory oversight to prevent unskilled users of radiation from embarrassing the medical profession by questionable practices.

Finally, the effects of corporate pressure from manufacturers in a state that does not have a program cannot be underestimated. Alternative D would mean that, in order for facilities in any state to use byproduct materials, that state would have to establish a regulatory program that includes reactor-generated byproduct material. The NRC and its Agreement States would continue to regulate the *manufacture* of byproduct material for use in radiation devices and radiopharmaceuticals; thus, manufacturers would not be able to distribute radioactive byproduct material to users unless they were licensed by their states. Consequently, this requirement provides an inducement to states to expand or revise their existing radiation control programs to include byproducts.

Functions of the Federal Agency

A federal presence might serve a variety of purposes. These are discussed below.

Assisting states. As the Non-Agreement States prepared to implement their regulations, this federal agency could offer assistance in several ways. These include helping the states establish regulatory offices, training state radiation control personnel,[2] building liaisons between smaller states that want to share regulatory systems, developing survey methodology and instruments, and monitoring the success of these public radiation programs.

Investigating crises. When serious problems occurred, such as the Indiana, Pennsylvania, incident, this federal agency could investigate the incident and act as liaison to the media, much as the National Transportation Safety Board does in cases of airplane disasters. Without an independent investigative body that is activated in these instances, it is quite likely that, should a serious radiation incident occur in the future, Congress and the public would simply renew their urgent call for federal control of ionizing radiation in medicine.

[2] The committee believes that training of health care personnel involved in radiation medicine (i.e., physicians, technologists, nurses, health physicists) should be addressed by the states, professional societies, and health care institutions.

Educating the public. The actual risk involved in ionizing radiation in medicine is small compared to what is believed to be the public's perception of the risk. One activity of such a federal agency could be to correct this imbalance through education and information dissemination. It could also perform a valuable service by informing patients about measures that physicians should take to minimize the dose or risk from certain procedures, for example, avoiding x-rays during pregnancy and using gonadal shielding. This type of public education program could assist in putting radiation risk in a more accurate and balanced perspective.

Monitoring the effect of deregulation. This agency could monitor the effects of the shift in power and responsibility to the states. It could function as a data gatherer itself or as a clearinghouse for data collected by states or other federal agencies, with the task of issuing reports on how well the new regulatory scheme is working.[3]

Collecting risk data. Scant data are currently available on the risks of ionizing radiation in medicine, as discussed in Chapter 4. Byproduct misadministrations are reported to the NRC and adverse events for investigational drugs and blood products must be reported to the FDA, but data on adverse events involving other sources of ionizing radiation in medicine are reported on a voluntary basis, and are therefore either not available for comparison or underreported. This federal agency could gather such data (or act as a clearinghouse). Over time, this would enable the CRCPD and states to fine-tune their regulations more effectively.[4]

Conducting research. This federal agency could study, investigate, or conduct or fund research on the impact of new technology. In this way, it could help to reduce exposure and the risks of new technology. It could also identify high-priority areas for research and encourage other federal agencies, such as the National Institutes of Health, to support such work.

As noted previously in this report, the majority of states have some form of regulatory program in place. The approach assumed for Alternative D could have the effect of encouraging all states and federal health facilities (e.g., those administered by DOD, VA, PHS) to expand the scope of their existing regulations to cover all ionizing radiation in medicine, including byproduct material.

[3] The committee is not recommending the use of performance indicators as the concept is understood by the NRC, because this alternative does not retain the current Agreement/Non-Agreement State distinction.

[4] Data collection on the effects of long-term, low-dose exposures to radiation would not fall within the purview of this agency, but could be addressed by the scientific community.

Those states that currently do not have a comprehensive radiation safety program would have the following options:

- adopt the *SSRCR* (to address NARM and byproduct regulation) and set up an inspection and enforcement mechanism within the state agency;
- adopt the *SSRCR* through their own legislative process but join a consortium of states for the purposes of implementation and oversight formally authorizing another state to assume responsibility for an effective radiation safety program;
- require facilities to obtain inspection through a private, third party; or
- decide to have no state regulation of reactor-generated byproduct material.

The federal facilities (DOD, VA, PHS) would be encouraged either to expand their existing institutional procedures for NARM to include byproducts or to adopt the *SSRCR* for byproduct material.

Pro

Alternative D has all the putative strengths of Alternative C. To these it adds the advantage of a federal agency that could act as a catalyst and provide nonregulatory oversight and leadership to the state programs. This would, in turn, effectively encourage consistency across the nation by providing training to state officials, helping set priorities for action concerning various radiation sources, and assisting in the development of survey instruments and test methodologies.

This alternative would ensure that, in order for facilities within its borders to use byproduct materials, a state would have to establish a regulatory program that includes reactor-generated byproduct material. The committee expects that the states would expand existing programs for regulating non-byproduct sources of radiation to include byproduct material as well. If, however, a state decided not to expand its radiation safety program to include byproduct material, users in that state would not be able to obtain byproduct material.

The NRC and its Agreement States, as stated at the outset of this chapter, would retain responsibility for licensing the production of byproduct material for use in radiation devices and radiopharmaceuticals. These manufacturers must adhere to regulations that include distributing radioactive byproduct material only to NRC- or state-licensed users. Consequently, this requirement provides an inducement to states to expand or revise their existing radiation control programs to include byproducts. Alternatively, it forces users in states without programs that incorporate byproducts to use only accelerator-produced radiopharmaceuticals and devices that use accelerator-produced radiopharmaceuticals.

In addition, with the elimination of the NRC from regulation of ionizing radiation in medicine, this new agency's leadership role would assume significance

greater than that of previous federal attempts at centralizing control over the use of radiation. Put another way, such an agency would assume a leadership role for this activity for the federal government as a whole. It could assist the states in several ways, by providing funding to ensure that state development of model laws and regulations continues and giving warnings of possible dangerous situations in some states.

Con

This federal agency would require funds, although such requirements could be minimal. Because the NRC is supported by user fees rather than taxpayer dollars, Congress might be reluctant to appropriate the funds for even the minimal expenses of this agency. If so, Congress could devise a system of user fees to support the agency's activities. For example, a federal license could be established for each individual or facility using ionizing radiation in medicine. The fee associated with this license would be similar to those that physicians now pay for licenses that permit them to prescribe narcotics. A database of license payments would serve to identify the users of radiation, providing a means for communicating with them when necessary. These fees could probably be considerably lower than existing NRC license fees, because they would no longer need to support the regulatory apparatus that now exists there. Likewise, the states could also institute a system of user fees that would provide them with essential funding for expanding their radiation safety control programs to include reactor-generated byproduct material. Part of these fees would need to go to the CRCPD, which currently depends on funding from those federal agencies, including the NRC, that regulate the use of ionizing radiation.

The committee believed that if the Congress elected to adopt the proposals set fourth in this report, then it would set out some steps by which to facilitate implementation. In this regard, the committee thought that Congress would decide to rely exclusively on user fees (as mentioned herein), to develop some other mechanism for funding the proposed agency, or to devise some hybrid funding approach. It is also possible that Congress would explicitly direct the Secretary of the DHHS to develop strategies that would ensure sufficient funding for the proposed agency.

In addition, the presumption that the NRC would no longer help to fund the CRCPD may not be entirely accurate. The NRC might well drop its support for that aspect of the CRCPD that addresses the medical use of byproducts if Alternative D is adopted.

Presumably, however, the NRC would continue to fund the CRCPD's efforts with respect to all of the remaining *nonmedical* uses of byproducts (e.g., industrial, educational, and nonmedical research). Consequently, it is not known to what extent, if at all, the NRC would cease to fund the CRCPD. Furthermore, because the use of medical byproducts is a minuscule percentage of what the

NRC does overall, the amount of its CRCPD funding attributed to medical byproducts is small.

In short, the CRCPD is not threatened by potential dissolution. It derives funding from a variety of federal agencies, including the FDA and EPA, and it would be expected to continue its operations because of its important role in matters concerning all other remaining areas of radiation control.

This federal agency could not guarantee either the quality of any state program or the safety of ionizing radiation in medicine. The committee sees no reason, however, to assume that the states would discontinue their existing programs for regulating non-byproduct radiation. Rather, it is presumed, based on their existing radiation control programs, that states would expand these programs to include byproduct material as well.

Alternative E: Reserve Federal Authority

This alternative moves the regulation of ionizing radiation in medicine one step further toward a federal regulatory presence on the continuum. Specifically, it empowers the federal agency identified in Alternative D to exercise regulatory authority over any state unwilling or unable to enact a regulatory structure that encompasses ionizing radiation in medicine.

This alternative would identify a federal agency as described in Alternative D, other than the NRC, primarily to exercise a leadership role in the radiation safety community. This federal agency, most likely within the DHHS, would assist in developing recommended state laws and regulations for all ionizing radiation in medicine; in doing so, it would build on the already established and effective *SSRCR*. This agency would work in conjunction with the CRCPD and other professional organizations to enhance the existing *SSRCR* and to promote their adoption, thereby encouraging greater regulatory uniformity among the states. This agency would serve a variety of purposes and assume responsibility for several functions; these include (but are not limited to) assisting states, investigating crises, educating the public, monitoring the effect of deregulation, collecting risk data, and conducting research. These functions would be analogous to those set out in Alternative D.

The most critical feature distinguishing Alternatives D and E pertains to a situation in which a state does not elect to devise a program for regulation of ionizing radiation or rescinds an existing program because of economic or other considerations.

As explained in the description of Alternative D, federal agencies would still retain responsibility for regulation in certain areas. For example, the FDA would continue to regulate the safety and efficacy of radiopharmaceuticals and radiation-emitting medical devices. It would also continue to require the reporting of problems with medical devices and radiopharmaceuticals subject to the Safe Medical Device Act and to issue "alerts" warning all providers of problems with

medical devices and radiopharmaceuticals. The DOT would continue to regulate the transportation of byproduct materials. Regulation of the use of byproduct materials in medicine, along with NARM and machine-produced radiation, however, would now be the responsibility of the states, except at federal health facilities such as those operated by DOD, VA, and PHS.

As discussed in Alternative D, almost all states have some regulatory program in place. However, Alternative E would encourage all states and the federal departments that operate their own health facilities to expand the scope of their regulations to all ionizing radiation in medicine (reactor-generated byproduct material, NARM, and machine produced). Any state that currently does not have a radiation safety program that is comprehensive for all sources used in medicine would have the following options:

- adopt the *SSRCR* and set up an enforcement mechanism within a state agency;
- adopt the *SSRCR* through its own legislative process but join a consortium of states for the purposes of implementation and oversight, formally authorizing another state to assume responsibility for an effective radiation safety program; or
- refuse to adopt a program or include reactor-generated byproduct material within its existing radiation safety program.

In the event that a state does not establish or expand its existing radiation control program, it would become subject to the regulations for reactor-generated byproduct material devised for federal medical centers within the DOD, VA, and PHS. The federal agency would have authority to enforce this last option only if a state does not assume any responsibility to protect adequately the public health and safety of its citizens. This authority would be analogous to the NRC's authority today; in effect it would entitle the federal agency to resume regulatory authority over an Agreement State that has failed to establish an adequate program.

Pro

Alternative E has all the advantages of Alternatives C and D. It goes one step further than Alternative D by giving regulatory authority to the federal agency in a situation of last resort, namely, no state program. The primary role of the federal agency would be, as in Alternative D, to act as a catalyst and provide nonregulatory oversight and leadership to the state programs, thereby assuring consistency, providing training, helping set priorities for action among various radiation sources, and helping in the development of survey instruments and test methodologies. The agency's regulatory authority would be activated only when

a state has no protections devised to ensure the health and safety of its citizens pertaining to byproduct materials.

Placing the DHHS in the leadership role, based on its history of involvement in radiation issues and its public health orientation, may yield more reasonable regulations, if they are needed. Otherwise the agency would provide funding to ensure that state development of model laws and regulations continues.

Con

Incorporating a legislative provision that authorizes the federal agency to regulate states that have no program raises the following issues. First, what minimum level of regulation would be required by the states to prevent federal regulation? The federal agency would need to establish baseline minimum standards that each state must satisfy. Second, what evaluation mechanism would be set in place to assess the programs enacted by the states? In effect, this proposal could replicate, within the DHHS, the existing NRC Agreement State program, which permits states to enter formal agreements with the NRC to regulate reactor-generated byproduct material and necessitates that each Agreement State adopt programs virtually identical to the NRC's program for Non-Agreement States. Third, how elaborate might the federal structure need to be to accommodate a small number of states?

This federal agency would require more funds than the one described in Alternative D to address the potential need for exercising regulatory authority. The experience that is being gained in the MQSA program could be used to estimate the resources needed for this program. Congress might be reluctant to appropriate the funds for even the minimal expenses of this agency, but a system of user fees could be devised to support part of the agency's activities. One problem with this option is that legislation will need to be passed to establish that federal law preempts state law if a state does nothing.

Most notably, the drawback with this alternative is the delegation of federal regulatory authority for what is likely to be a minority of states. At the present time virtually all states have some form of regulation for radiation control.

Alternative F:Centralization of Regulation Within One Federal Agency

The committee believed that certain advantages could be realized if all ionizing radiation in medicine were treated in a similar manner. For this reason, the committee considered another option that would grant a federal agency regulatory responsibility not only for byproduct materials, but also for NARM and machine-produced radiation used in medicine. This responsibility could range from setting minimum standards and encouraging the states to implement these

standards to establishing stringent federal regulations and enforcing them rigorously.

The major change wrought by Alternative F would be to usher in the federalization of all regulation of ionizing radiation medicine. The federal government would be given the authority to regulate all of ionizing radiation in medicine. It would also be responsible for writing standards, for ensuring technician training, for licensing users, and for inspection of x-ray machines and other devices. This alternative, unifying all regulation at the federal level, would result in a major expansion of federal responsibility.

This federal regulatory apparatus could be housed in any of the federal agencies that have regulatory responsibility for some aspect of ionizing radiation. The two likely candidates would be the DHHS and the NRC. If Alternative F were adopted, the committee would recommend centralization within the DHHS because it is best suited to administer public health programs and because it already has various levels of authority over ionizing radiation in medicine. The likely entity within the DHHS is the FDA, specifically the Center for Devices and Radiological Health; however, a new division within the FDA might also be created.

The committee believes that for appropriate regulation of ionizing radiation in medicine, knowledge and experience with the medical issues should be emphasized over knowledge and experience with byproduct materials. Furthermore, were a new federally centralized apparatus to be housed within the NRC, the NRC's legislative authority would have to be expanded a great deal because it now has jurisdiction only over byproduct materials, which, as discussed in Chapter 4, account for only about 10 percent of ionizing radiation in medicine. The committee did not further examine placement of this agency with the NRC, therefore, for both these practical reasons and the fact that it would leave in place, if not exacerbate, the problems already laid out in Chapters 3 and 4.

The committee gave considerable attention to the fiscal arrangements of Alternative F, assuming the federal agency were to be in the DHHS. Presumably (although not inevitably), this new DHHS agency would be subject to user fee requirements like those Congress imposed on the NRC. If a DHHS-based system allowed states to become Agreement States, then those that chose to do so would stop contributing fees to support the agency's activities. Thus, even though the agency would continue to develop standards for all states, the remaining Non-Agreement States would be forced to bear an ever larger fraction of the financial support required for these tasks. This financial pressure would likely drive all states to become Agreement States (as is now the trend with the NRC-based system for byproducts alone), leaving the agency with no revenue to pay for its standard-setting functions.

One way to avoid this within Alternative F would be to separate the budget for standard-setting functions from that for enforcement functions. The costs of the former would be spread across all regulated institutions, whether in Agreement

or Non-Agreement States. Only Non-Agreement States' institutions would be charged the cost of federal enforcement functions.

Pro

Alternative F unifies all regulation of radiation medicine at the federal level, a factor that supports the committee's aim of promoting uniformity across all modalities in radiation medicine. It also provides a mechanism for dealing with those states that do not wish to take on the responsibility for regulation should the NRC cease to regulate under 10 CFR Part 35, as proposed in Alternative A2 (above) and the committee formally recommends in Chapter 6. This DHHS agency could, under this system, issue mandatory minimum standards for all radiation use in the healing arts, including x-rays, linear accelerators, and cyclotrons. It could also carry out technician training and licensure and inspection of radiation-producing machines. It would be able to provide a consistent regulatory approach for all sources of ionizing radiation in medicine based on consistent radiation protection criteria, derived from the National Commission on Radiation Protection and Measurements guidelines or the EPA's federal guidelines. It would assure that every person in the country who needs ionizing radiation for diagnosis or treatment would have it administered by a program held to national standards. All licensees would be subject to the federal regulations, whether implemented through some arrangement with the states or by the federal government.

The appeal of Alternatives D and E, which enable a federal entity to assume a role in such functions as leadership, education, research, and data collection, applies to this alternative as well. Alternative F would undoubtedly include the above-mentioned functions and perhaps others.

Con

The cost of this program at the federal level would almost certainly be greater than either the existing NRC regulatory activities or any of the previously described alternatives, because Alternative F ushers in the federalization of *all* regulation of radiation medicine. That is, it not only unifies but also greatly expands regulation at the federal level. It would also require legislation to transfer the regulatory responsibility from the NRC to the DHHS, as well as new enabling legislation, rulemaking, and regulations in the DHHS.

Although Alternative F comes closest to centralizing responsibility in one agency of any of the alternatives described to this point, true uniformity is impossible to achieve. This fact undercuts the attractiveness of this alternative. The complicated reality of radiation regulation, which involves the participation of several agencies, including the DOT, EPA, and the Occupational Safety and

Health Administration, makes successful centralization of all regulatory functions within the DHHS simply not feasible.

Alternative F would not change the present scheme of regulating the nonmedical uses of byproduct material. Inconsistencies could develop between the regulation of medical and nonmedical applications unless the DHHS and the NRC worked closely together. Some aspects of basic radiation protection (personnel dosimetry, limits of occupational and general population exposure) in 10 CFR Part 20 apply in both medical and nonmedical settings. If the NRC remained responsible for the regulation of Part 20, then elements of Part 20 would have to be enforced by both the DHHS (medical) and the NRC (nonmedical). Consequently, even Alternative F does not unify all regulations pertaining to ionizing radiation. That issue, however, is a multifaceted and complicated regulatory problem that is beyond the committee's purview and expertise.

Alternative G: Health Finance Agency

As was clear from all the materials reviewed and activities pursued by this committee, regions of the country differ vastly in their uses of medical procedures, reimbursement levels, and methods for delivery of health care. When viewed together, the various approaches to health care organizations are seen as scattered, inconsistent, and decentralized. Some on the committee were uncomfortable with this degree of decentralization, an issue the committee considered by weighing the points set out in Alternative G. Alternative G would place regulatory authority into a single, centralized agency to counter inconsistency and inefficiency.

The key point to this alternative is that it would not be limited to regulating ionizing radiation in medicine. Rather, it would eschew changes like those in the alternatives described above in favor of creating an entire health care financing and regulatory apparatus that is coordinated, accountable, and subject to budget controls.

Specifically, Alternative G would create a Health Finance Agency (HFA), which would, as in Alternative F, acquire regulatory power currently held by the NRC (its medical component) and by parts of the DHHS. In addition, the HFA would have authority over reimbursement for all DHHS programs, such as Medicare and Medicaid. This agency would also have power to regulate health care, broadly eliminating practices that were shown not to be effective or beneficial. The HFA could conduct clinical trials and other studies to determine what procedures were cost-effective. Establishment of an HFA would encourage greater uniformity in the practice of medicine and would help to exclude practitioners who were incompetent or dangerous. The HFA could also choose to limit choices of medical practitioners.

This is an extreme approach for addressing a very specific issue that focuses on one aspect of medicine. The committee recognizes that it is an unusual proposal

on a rather discrete issue and that it has not been developed to its full logical extension.

Pro

A major advantage of the HFA, which would control perhaps 14 percent of gross domestic product, would be its authority to determine which practitioners and procedures were not effective or beneficial and exclude them. It could improve minimal standards and work to ensure that everybody had access to treatment. If the system worked well, it could be efficient, equitable, transparent, and easy to administer; it would define the goals of safety and high-quality care and work to achieve them.

Con

The first-mentioned advantage of the HFA leads to its principal disadvantage: it would have almost complete power over the delivery of health care. If the system did not work well, it could be very inefficient and inequitable. Although the HFA would have the potential for increasing efficiency, equity, and the quality of care, the committee believes the health care system is inherently too complicated and diverse to be centrally administered in this way. There are legitimate differences in the incidence of disease, conditions, and what can be expected from the patient in different demographic and geographical areas. A centralized system would inevitably mean a large increase in bureaucracy and reduce provider incentives and responsibility. Diversity, provider responsibility, and the ability of consumers to select their care givers are fundamental strengths of the current medical care system. These characteristics of the health care sector remain highly valued, and they might be inconsistent with the centralized and bureaucratic elements that must be assumed for Alternative G.

ASSESSMENT OF THE ALTERNATIVES

Alternatives Eliminated from Consideration

The committee chose the seven alternatives described above as representative of a wide theoretical range. Each addresses problems with the current system, applying a particular solution. The committee devoted careful attention to clarifying the major underlying problems, crafting possible solutions, analyzing the alternatives. As mentioned earlier, in all of the alternatives, with the exception of Alternative B, several federal agencies retain regulatory control over various aspects of radiation used in medicine. The discussion of the alternatives will examine the extremes and move toward the preferred alternative.

The committee rejected retaining the status quo described in Alternative A, even in its modified form (A2), essentially because it does not address the committee's concern that all ionizing radiation in medicine be administered and regulated more consistently. The existing inequity between byproduct material and NARM and machine-produced radiation remains unchanged: intensive regulation of byproduct material at the federal level and no federal regulation of the uses of other sources of radioactivity.

The committee also rejected the laissez-faire approach in Alternative B. Although laissez-faire markets work well for many goods and services, the market for health care is distinctive for several reasons. These include the fact that health insurance insulates people from the true price of medical services.

Additionally, at the point at which patients must make sensitive choices about illness and health care, they may be distraught, lack sufficient or appropriate information, and find it difficult to think systematically about their options. These problems may arise from a number of factors; for instance, their physicians may not themselves understand the probabilities of risks and benefits of all therapeutic options or may not communicate that information in ways that patients find helpful. The challenges of communicating such information are particularly serious for medical uses of radiation, because the problems of excessive radiation exposure can be subtle and not likely to occur for many years. For these reasons, patients may find it hard to appreciate the full set of benefits and risks of alternative procedures involving the use of ionizing radiation (or to weigh those benefits and risks against those of alternative procedures not involving radiation) or to understand the risks of procedures that are done poorly. To the extent that this is so, they will not be able to enter into appropriate, fully informed decisionmaking with their physicians.

As mentioned earlier, many committee members were not convinced that the marketplace, the malpractice system, and the watchful eyes of professional societies, by themselves, could weed out incompetent practitioners and ineffective procedures. Because Alternative B precludes a governmental role in maintaining standards, the committee was concerned that the quality of the delivery of ionizing radiation in medicine would sink to a lowest common denominator, a level considered too risky even by those who believe that the existing regulatory system is incommensurate with the actual risks associated with ionizing radiation. Finally, the committee recognized that this laissez-faire approach would be unacceptable to most Americans.

Moving to the other extreme of the scale, the committee then rejected the HFA in Alternative G. This alternative, rather than letting providers and patients make choices essentially without government interference, could limit choices available to them. The HFA would set guidelines for appropriate health care interventions and then enforce compliance with those guidelines through nonpayment, exclusion from federal programs, or similar regulatory steps. The crucial problem for the committee is that such guidelines and regulatory actions

would, as this alternative was envisioned, necessarily extend beyond the use of ionizing radiation to cover all aspects of health care. The committee, asked to address a very specific problem regarding regulation of ionizing radiation in medicine, was unwilling to recommend this all-encompassing and overwhelming solution. Promoting such a system might or might not result in much needed controls of escalating health care costs or expand access to care, but neither Congress nor the country as a whole, in the view of the committee, is prepared for such a massive reorganization of the health care system.

Alternative F, which centralizes regulation of ionizing radiation in one federal agency, has several appealing characteristics. It would achieve regulatory clarity and simplicity by transferring the authority to regulate ionizing radiation in medicine to an agency responsible for federal oversight of health care. However, as the committee explored this alternative, it could find little reason for creating an *expanded* federal role in the regulation of accelerator-produced radionuclides and machine-produced radiation—that is, to 90 percent of radiation medicine now regulated at the state level. Although some committee members thought that safety should be increased and usage reduced for some radiation sources, such as x-ray machines, they did not see this as the job of the federal government. A federal agency might fund research, foster professional consensus, or advocate improved health care, but in the committee's view a federal regulatory agency responsible for all uses of ionizing radiation in medicine would be expensive, unwieldy, and too powerful. Although not a reason in and of itself to preclude such an expansion, such a change would require time-consuming enabling legislation. From a cost-benefit perspective, the committee as a whole saw little reason to pursue this alternative.

Thus, the committee narrowed down the alternatives to C (state control), D (federal guidance), and E (reserve federal authority). The committee found many appealing qualities in Alternative C, in which all regulatory authority is given to the states. Although several federal agencies regulate radiopharmaceuticals, radiation-emitting medical devices, transport of radionuclides, and radiation exposure of workers and the public, most states regulate the use of all ionizing radiation in medicine except for byproduct materials. State government is, therefore, a logical locus for more comprehensive regulation of these modalities. Although this system is not always perfect, it seems to function to the satisfaction of the public, its representatives, and health care practitioners. Because the committee sees little difference between radionuclides generated naturally or by accelerator or reactor, and because state regulation of the first two sources appears to be working well, the committee concluded that primary state regulation would be appropriate.

In the end, the committee was not comfortable with this possibility. The committee was concerned that state regulation of ionizing radiation evolve in accordance with scientific and technological advances; that Non-Agreement States be assisted with any transition from NRC regulation; and that information

sharing and monitoring of the general public health and safety be enhanced. In the end, the committee elected not to endorse Alternative C.

Alternative E is similar to Alternative D, But in addition provides for the exercise of limited federal authority, through the licensing of user sites and users, if a state chooses not to expand its radiation control program to include byproducts. This is the primary difference between these two alternatives. The committee's concern about Alternative E focused on the delegation of federal regulatory authority for what is likely to be a minority of states. Federal regulation of states without a program for byproducts also calls into question what minimum level of regulation would be required and the need to establish minimum standards. In effect, this alternative could replicate the existing NRC Agreement State program with potentially all the peculiar funding characteristics and practical drawbacks that are now apparent in the NRC approach. Thus, the committee arrived at its preferred choice: Alternative D.

Alternative D: The Preferred Alternative

Alternative D modifies state regulation (Alternative C) by adding a federal agency with two key roles: (1) it would be responsible for working in conjunction with the CRCPD and other professional organizations to provide voluntary guidelines and model regulations for states, and (2) it would assume a leadership role for the regulated community.

Although, under Alternative D, states cannot be compelled to accept the voluntary guidelines or *SSRCR*, a variety of forces can greatly influence them to do so. For example, the committee envisions a collaborative effort of the proposed federal agency, the states, the CRCPD, and other professional organizations not unlike the process utilized in developing the mammography regulations that involved the FDA, the American College of Radiology, and other professional organizations. This would facilitate an interactive process, allowing an exchange of ideas, so that controversies might be resolved before implementation. Respect for and investment in the process would foster a keen vested interest in successful implementation on the part of all participants.

Other reasons exist for states to adopt voluntary guidelines and the *SSRCR*. Professional peer pressure, from the people within each state who are involved in developing the *SSRCR*, would exert substantial influence to make the process work. Consumer groups and the media, seeking to ensure that the citizenry is protected, would also exert pressure. State medical societies would also want regulatory oversight to prevent unskilled users of radiation from embarrassing the medical profession by their questionable practices.

Finally, corporate pressure from manufacturers in a state that does not have a program cannot be underestimated. Alternative D would mean that, for facilities in any state to use byproduct materials, that state would have to establish a regulatory program that includes reactor-generated byproduct material. The NRC

and its Agreement States would continue to regulate the *manufacture* of byproduct material for use in radiation devices and radiopharmaceuticals; thus, manufacturers would not be able to distribute radioactive byproduct material to users unless they were licensed by their states. Consequently, this requirement provides an inducement to states to expand or revise their existing radiation control programs to include byproducts.

The committee was concerned that a purely voluntary agency, sustained by states or professional associations or both, such as the CRCPD, might receive insufficient funding during periods when states had fiscal crises. A modest federal presence could head off potential difficulties at what the committee believed would be a relatively low cost.

The committee determined that this agency should be one other than the NRC, because the NRC's mission is to regulate only those materials used in medicine that are products of nuclear reactors. The NRC, therefore, has responsibility for only 10 percent of ionizing radiation in medicine. The more logical choice for a responsible agency would be the DHHS, which has an extensive history in regulating radiation.

Eliminating federal regulation of byproducts made some committee members apprehensive about the possibility of decrements in quality of care. This point was discussed at great length during this study. The committee's conclusion that Alternative D was sufficient to protect quality of care and public health rested on several considerations.

The first was that current federal regulation of pharmaceuticals, medical devices, equipment, transport, disposal, and worker and public exposure would continue under Alternative D. In addition, the federal government would have to regulate the use of ionizing radiation in medicine in the PHS, VA, and DOD medical facilities. Moreover, nothing in this alternative would weaken current licensure or certification requirements for physicians and other health workers. Radionuclides per se would continue to be regulated stringently to ensure that they do not injure the public.

Second, the NRC would retain responsibility for licensing both manufacturers of byproduct material (nuclear power plants) and producers of radioactive products (i.e., radiopharmaceutical companies). These producers, adhering to federal regulations for their licensure, could not legally sell byproducts to unlicensed users. Consequently, states are induced to expand their existing radiation control programs to include byproducts, or users within their borders would be unable to obtain byproduct materials.

Third, millions of patients have been treated with machine-produced radiation and accelerator-produced radionuclides with no indication of patient or public injury beyond that common to medical care procedures in general. Current state regulations seem to work for non-byproduct ionizing radiation in medicine, which accounts for 90 percent of ionizing radiation used in medicine, and the committee expects that byproduct materials can be accommodated in the

state systems. The burden is on the states to protect the public health and safety of their citizens adequately by devising effective regulatory programs that encompass byproducts. Because the states already provide effective regulation for non-byproduct radiation in medicine, the committee sees no good argument for subjecting all of radiation medicine to federal regulation for the first time.

Nonetheless, the presence of a federal agency, the purpose of which is leadership and guidance rather than regulation, could add a great deal to the effectiveness of a state-based regulatory system. As discussed above, the federal agency as envisioned in Alternative D would fulfill several functions: assisting states in establishing regulatory programs, training inspectors, addressing problematic incidents of national concern, educating the public as to the benefits and risks of radiation medicine, collecting risk data so that more informed policy decisions might be made by the states, conducting research so that the science of radiation medicine continues to advance, and monitoring the effects of deregulation. By acting in these traditional capacities, the federal agency would add to the safe administration of ionizing radiation in medicine without imposing more requirements on one aspect of ionizing radiation than on another.

CHAPTER SUMMARY

The committee defined a wide range of alternatives for the regulation of ionizing radiation in medicine. It then sought to elucidate both strengths and problems within each option and to identify the alternative most likely to deliver the greatest net benefit to society. Having considered everything from the status quo to a system of laissez faire to a complete centralization of all medical regulation, the committee chose Alternative D, as described above. The next chapter presents the committee's findings and conclusions, and makes recommendations for the implementation of Alternative D.

6

Findings, Conclusions, and Recommendations

In response to the three major goals defined by the Nuclear Regulatory Commission (NRC), the committee has addressed:

- the broad policy issues that underlie the regulation of medical uses of radionuclides;
- the overall risks associated with the use of ionizing radiation in medicine, assessing the error rates and consequences of the use of byproduct materials in comparison to other forms of ionizing radiation and other medical modalities; and
- the current statutory and regulatory framework for the control of medical uses of byproduct materials and a uniform national approach to the regulation of ionizing radiation in all medical applications.

This final chapter first sets out two premises of the report: (1) that regulation of ionizing radiation in medicine warrants as rigorous an analysis of the costs and benefits of such regulation as the data will permit, and (2) that states have the ability to regulate radiation effectively within their borders. Next, the chapter lays out the committee's findings. These are followed by a discussion of the committee's conclusions and of its eight recommendations, which include suggestions for action that might be taken immediately and plans for long-range adjustment of the regulatory system. The recommendations are based upon the committee's endorsement of Alternative D (federal guidance) in Chapter 5.

REPORT PREMISES

The underlying premise of this report is that a balance must be achieved between the benefits and costs of regulation. In an ideal world of limitless resources, risks could be reduced to their minimum possible level. In reality, however, resources are not infinite. Policymakers must determine where scarce resources ought to be applied. Within the medical context, innumerable areas require attention. Resources committed to reducing the risk of adverse events in one area of medicine might be better committed elsewhere.

The concentration of resources spent to reduce adverse events involving byproduct material, although seemingly effective, appears to have gone beyond the point at which the additional dollar spent on regulation achieves an equivalent dollar of benefit. The implication is that decreasing somewhat the resources directed at regulation may not pose commensurate risks or, similarly, may yield benefits in the form of resources that can be put to better or more efficient use. In the judgment of the committee, reduction of NRC regulatory authority will not increase the incidence of adverse events significantly, if at all.

The intensity with which the byproduct area of radiation medicine is being regulated at the federal level—while the rest of ionizing radiation used in medicine and, indeed, most of the rest of medical practice remains free from this level of federal oversight—has little if any justification. Moreover, no clear reason exists for singling out this particular facet of ionizing radiation in medicine for such tightly controlled regulation. One might, theoretically, regulate all of medicine at the federal level to ensure greater uniformity, but the committee recognized that such an improbable restructuring of the total medical system would entail great cost, not achieve complete uniformity (due to how widely disseminated regulatory responsibility for radiation presently is), and yield questionable results for the resources expended.

Second, at the crux of this report lies a fundamental philosophical and political perspective concerning state and federal regulation. All of ionizing radiation, with the exception of byproduct material, is currently regulated at the state level. No evidence of major problems with state regulation has ever been documented. The committee, of course, cannot know whether states will continue their regulatory programs. The committee judged, however, given the strength and leadership of the Conference of Radiation Control Program Directors (CRCPD) and the *Suggested State Regulations for the Control of Radiation* (*SSRCR*) it promulgates, that state radiation programs would remain intact and expand to the area of byproduct use if federal regulation in this area is relaxed. Thus, all sources of ionizing radiation would be treated more uniformly than before, in that they would *all* be subject to state regulation. Admittedly, the extent of state regulatory programs varies, but for the majority, the *SSRCR* are the common denominator nationwide.

FINDINGS

During its deliberations, the committee reviewed information from a variety of sources, including commissioned papers, literature reviews, site visits, official presentations by NRC personnel, a public hearing, and interviews with radiation safety officers. The lack of data for comparing byproduct material, naturally occurring and accelerator-produced radioactive materials (NARM), and machine-produced radiation limited the scientific basis of the committee's findings. This section enumerates the findings the committee generally agreed upon given the existing data, as presented in Chapters 2, 3, and 4. The issues are summarized in terms of risks and benefits, regulations, the regulated community, and private and voluntary involvement in radiation safety.

Risks and Benefits

1. The use of ionizing radiation in medicine offers tremendous benefits to patients but also carries a nontrivial potential for harm.
2. Compared to the regulatory systems in place for the other 90 percent of medical use of ionizing radiation, the more detailed reporting and enforcement systems required for byproduct materials do not seem to result in even a marginal decrease in risk to providers, patients, or members of the public.
3. Equal treatment of all ionizing radiation in medicine would be a sensible national policy insofar as the risks of reactor-generated byproduct material and other forms of radiation are equal. However, because data on adverse events in the use of ionizing radiation are limited, it is difficult to compare risks involving byproduct material with risks involving machine-produced radiation, or to compare overall risks of the use of ionizing radiation in medicine with those of other medical modalities.

Regulations

1. The fragmented regulation of the use of ionizing radiation in medicine —namely, its division into (a) the NRC's exclusive regulation of reactor-generated byproduct material, and (b) state regulation of NARM and machine-produced radiation—is a historical artifact. This has resulted in appreciable variation in the intensity and nature of regulatory control of various forms of radiation that have roughly equivalent risks.
2. Regulation of reactor-generated byproducts exceeds in intensity and burden that of all other aspects of ionizing radiation in medicine. The regulation of reactor-generated byproduct material is also more vigorous than that of any other aspect of high-risk health care. It greatly exceeds the regulation of chemotherapy, surgery, anesthesia, and the use of general pharmaceuticals except for controlled substances, all of which are unregulated at the federal level.

3. Regulatory guides, such as the NRC's "as low as reasonably achievable" regulatory guide, that do not require formal public discussion become in effect enforceable regulations because institutions often must demonstrate compliance with the guides to get their licenses renewed.
4. As more states become Agreement States, the institutions in the shrinking number of Non-Agreement States experience significant increases in fees to continue to support the NRC's Medical Use Program, which relies exclusively on user fees for funding.
5. In addition to the regulations written by the NRC, other federal regulations exist to protect the public from potential harm caused by radiation. These include regulations from the Food and Drug Administration (FDA) within the Department of Health and Human Services (DHHS), the Department of Transportation (DOT), and the Environmental Protection Agency (EPA).

The Regulated Community

1. The regulated community has expressed interest in an external regulatory presence. Some parts of the community specify a desire for a federal regulatory presence, while the majority appears to prefer a shift to state regulation.
2. Despite official cautions against overzealous inspection in the NRC inspection manual, the regulated community maintains that these cautions are virtually ignored by the inspectors.
3. The regulated community has expressed reservations about seeking advice from the NRC, fearing that it may become the target of punitive reprisals rather than assistance.

Private and Voluntary Involvement in Radiation Safety

1. Professional societies have taken an active role in developing guidelines and quality assurance programs and in fostering and setting standards for education and training in the area of safe and appropriate use of ionizing radiation in medicine.
2. Guidelines created by the CRCPD have been adopted to various degrees by states. Other professional groups and federal entities have also created standards and guidelines that can be adopted voluntarily by the states.

CONCLUSIONS

Modern medicine would be impossible without ionizing radiation. X-ray imaging, computed tomography scans, diagnostic and therapeutic nuclear medicine, brachytherapy, the gamma knife, and linear accelerators are a few of the technologies that have revolutionized medical diagnosis and treatment. As discussed in Chapter 2, radiation's benefits for human health can be measured in thousands of lives saved and even greater numbers of persons whose quality of

life has been improved each year by these technologies. Even though the use of ionizing radiation in medicine offers enormous benefits, however, it also poses potential risks to patients, medical personnel, and the general public. The diagnostic and therapeutic tools that cure also can cause acute injuries and chronic illness, such as cancer.

The committee recognizes both the tremendous benefits derived from the use of ionizing radiation in medicine and its potential for harm. The committee's goal is to promote the benefits while advocating a regulatory structure that adequately protects the health and safety of patients, workers, and the public. An important component to this balance is patient access to radiation medicine. Fewer people will benefit if regulation makes radiation medicine needlessly expensive or moves its tools a great distance from patients. Regulatory steps that lower the probability of risk only slightly, if at all, but seriously affect access through significant increases in cost and distance from patient populations should be foregone. The committee has identified and proposes to eliminate regulations that result in added costs but achieve little, if any, reduction in risk or additional benefit to a patient's outcome and well-being or that of health care personnel.

The committee has determined that the NRC's current regulatory procedures are unjustifiably intense and burdensome, that they may have compromised the availability of the benefits of radiation, and that they do not decrease the risks of medical use of ionizing radiation in any meaningful way. That is, current NRC regulatory policy, as embodied in the Medical Use Program, provides no obvious positive value to consumers or providers of health care.

The committee also concludes that it is appropriate to promote equal treatment of all ionizing radiation in medicine, insofar as the risks of reactor-generated byproduct material and those of other forms of radiation are equal, as set forth in Chapter 4. The most important difference between radiation sources is that machines produce radiation only when activated, whereas radionuclides produce radiation until they decay fully. In terms of their use in health care, this difference, which requires special considerations in the storage, shipping, and handling of radionuclides, is minor when compared to the similarities of the medical applications of the various types of radiation.

The regulatory system specifically covering the medical use of reactor-generated byproduct material has outlived its original logic. Nuclear medicine and radiation oncology expanded greatly with the availability of reactor byproduct material for peaceful uses, and it is understandable that the Atomic Energy Commission, and later the NRC, were at the outset delegated general authority for regulation in these fields, as described in Chapters 2 and 3. Today, however, many accelerator-produced radionuclides play a central role in the practice of nuclear medicine, and in radiation oncology, accelerator-produced radiation continues to displace the use of byproduct radiocobalt. Consequently, the unequal

treatment of different sources of ionizing radiation in medicine can be construed as illogical if not counterproductive.

The committee set out to determine what the appropriate level of regulation should be for all ionizing radiation in medicine. Taking the view that such regulation should be considered in its entirety, the committee concluded that special treatment of reactor-generated byproduct material is inappropriate and that the regulation that would be appropriate should not be conducted by the NRC, given that the risks are spread more or less evenly across all sources of ionizing radiation.

All these factors, taken together, argue for the need to remove regulatory authority over the use of byproduct material in medicine from the NRC and to replace it with a broader and more appropriate system for the regulation of all ionizing radiation in medicine. The committee identified its preference for Alternative D (federal guidance) (as discussed in Chapter 5) to achieve this result. Alternative D removes the NRC from regulating byproducts used in medicine, shifts responsibility for federal guidance to the DHHS, and delegates regulatory authority over the use of byproducts in medicine to the states, with the proviso that only licensed users will have access to byproduct material.

To effect this outcome, the committee outlines eight specific recommendations. The next section presents these recommendations in the form of (a) proposals for Congress, (b) steps for immediate action by the NRC, and (c) actions for professional entities.

RECOMMENDATIONS

A: Recommendations to Congress

A1. The committee recommends that Congress eliminate all aspects of the NRC's Medical Use Program, 10 CFR Part 35, and those regulatory activities conducted under 10 CFR Part 20 that are applicable to medical uses.

The committee proposes that Congress revoke the NRC's authority to regulate the medical and biomedical research uses of reactor-generated byproduct material. By nullifying the NRC's authority, Congress can effectively relinquish to each state, at its option, responsibility for regulation of reactor-generated byproduct material. Elimination of the NRC's Medical Use Program should only take place once the second recommendation to Congress (A2, below) has been fulfilled. Additionally, any legislation that accomplishes the revocation of Part 35 should provide for a transition period, during which the federal government transfers authority to the states.

Rescission of authority at the federal level for regulation of the medical use of byproduct material has three benefits. First, it eliminates prescriptive and

costly regulations that yield marginal risk reduction. Second, it shifts responsibility, by giving state governments authority over the health and safety of their citizens. Third, it promotes uniform treatment, in that radionuclides and machine-produced radiation are regulated by a single level of government at equal intensity, regardless of their source.

It should be emphasized, however, that the NRC would retain regulatory authority over manufacturers of byproduct materials used in medicine, such as nuclear power plants and radiopharmaceutical companies. Also, as mentioned in Chapter 5, other federal agencies, such as the FDA, the DOT, and the EPA, would retain their regulatory authority over radiation.

A2. The committee recommends that Congress direct the Secretary of Health and Human Services to support, coordinate, and encourage the following activities involving regulation of all ionizing radiation in medicine:

- **a. supporting the operation of the Conference of Radiation Control Program Directors;**
- **b. providing a venue for the review and evaluation of *Suggested State Regulations for Control of Radiation*;**
- **c. assisting states in implementation of their regulations;**
- **d. aiding in assessment of the effectiveness of state programs through the collection and analysis of data;**
- **e. helping develop survey methods by which the rate of adverse events for a wide range of procedures and devices might be measured;**
- **f. monitoring the effects of deregulation;**
- **g. enhancing training and standards for health care personnel; and**
- **h. investigating future significant radiation medicine incidents.**

The Secretary of the DHHS can accomplish the above functions either by creating a new office within the DHHS or by assigning these functions to an existing office, such as the FDA's Center for Devices and Radiological Health. The committee deliberately chooses not to suggest an exact location, as it believes that the Secretary is in a better position to make such a decision.

The committee recommends that the functions of this agency include the responsibility of funding the CRCPD and of encouraging and assisting the CRCPD in the continuous revisions of model legislation for adoption by the states. This "bully pulpit" role lends credibility to the CRCPD's efforts by giving it a federal imprimatur. Also, this nonregulatory federal entity, by convening the appropriate professional organizations to review and analyze new information that comes to light, provides a vehicle for integrating and coordinating efforts that will have national consequences.

B: Recommendations to the Nuclear Regulatory Commission

B1. The committee recommends that the NRC immediately relax enforcement of 10 CFR 35.32 and 35.33 through its present mechanisms.

Appreciative of the weight of the NRC's regulatory responsibilities, the committee nevertheless explored problems with the NRC's Medical Use Program that should be addressed. In hearings, committee members heard consistent criticisms of NRC regulations and enforcement as burdensome, costly, and overly prescriptive. The NRC's regulatory program for the industrial sector is based on the premise that radiation and people should be kept apart. In the medical context, radiation and people are intentionally brought together in an effort to improve health and save lives. Thus, the committee found that the regulated community's desire for a collegial, more cooperative approach on the part of the NRC could improve the quality of medical care and lower the rates of misadministrations.

The level at which the NRC currently enforces 10 CFR 35, sections 35.32 and 35.33—through detailed and voluminous documentation, reporting, and penalties—is inconsistent with the NRC's Medical Policy Statement, which favors minimum regulatory intrusion into the practice of medicine. Indeed, NRC's written regulations nowhere require such strict enforcement. The NRC has the authority to cease its present methods of enforcing sections 35.32 and 35.33, of its own volition. At a minimum, the NRC could immediately notify its licensees of its intent to relax its detailed enforcement and monitoring of sections 35.32 and 35.33, until a more permanent change is effected. This single change is a move toward bringing NRC regulations into line with the way that medical care in general and ionizing radiation in particular (except for byproduct materials) are regulated.

Reporting requirements currently in section 35.33 would not be entirely abandoned. On August 26, 1993, the NRC and the FDA created a memorandum of understanding to coordinate existing NRC and FDA regulatory programs for medical devices, drugs, and biological products that use byproduct, source, or special nuclear material. The committee urges the NRC to continue to cooperate with the FDA as provided in their memorandum of understanding to obtain data on devices, drugs, and biological products that relate to device malfunction, serious injury, and death. This coordinated effort between the two agencies will capture important data on technology and human (user) error related to device use but will exclude information relative to medical or technical judgment. This also reinforces the notion that the NRC, like the FDA, should not intervene in the practice of medicine.

B2. The committee recommends that the NRC initiate formal steps under the Administrative Procedure Act to revoke Part 35 in its entirety, if Congress fails to act within two years in response to the two recommendations to Congress stated above.

In addition to overly stringent enforcement, the regulations themselves are excessive and duplicative: 10 CFR Part 35 covers areas that either are already regulated at the institutional level or are best left to the states, to professional societies, and to patients in consultation with their doctors. States regulate the medical uses of other forms of ionizing radiation and, as discussed below, could easily fold byproduct material into their regulatory programs. The CRCPD could add byproduct material to its suggested state regulations. These additions could incorporate relevant concepts currently in Part 35 (see discussion below under Recommendation C1 to the CRCPD and states). The FDA collects data on adverse effects of radiopharmaceuticals and incidents of failure of radiation-emitting medical devices, and it could assume the monitoring responsibilities of the NRC.

Quality improvement programs are put in place by institutions and health plans, with the support of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and other private accreditation organizations. Doctors have ethical obligations, codified in professional standards, for informing patients of medical errors. The committee believes that the relatively low misadministration rate could be maintained by less stringent programs that are administered at the state level by professional societies, and by existing liability law.

The committee strongly endorses the formal route of notice and comment, subject to the Administrative Procedure Act, to accomplish the rescission of all of Part 35. The committee recognizes that this process will take some time.

B3. The committee recommends that the NRC separate the costs of formulating regulations from the costs of administering those regulations.

Fees cover both development and administration of regulations. Licensing fees charged to health care facilities to meet the cost of the existing NRC program are becoming increasingly expensive as more states become Agreement States. The reason is that the NRC program and overhead costs do not drop, but the costs are spread over institutions in fewer and fewer states.

Congress ordered the NRC to recover 100 percent of its costs from user fees, and thus all NRC costs have been divided among the institutions it licenses. Congress also permitted the NRC to discontinue its authority over states interested in entering into formal agreements with the NRC, becoming Agreement States subject to NRC oversight. These Agreement States do not bear any of the NRC's costs. As more states have decided to become Agreement States, the NRC's costs have declined somewhat, but not nearly in proportion to the number

of institutions it licenses. The result is rapidly rising fees levied on the institutions it does license, and this in turn increases the pressure for the remaining states to become Agreement States. This existing system is unfair. Only NRC-licensed institutions should bear the NRC's costs of licensing and inspection, whereas the costs of developing standards should be borne by all institutions, whether or not they are located in NRC-regulated states.

C: Recommendations to the Conference of Radiation Control Program Directors and to the States

C1. The committee recommends that the Conference of Radiation Control Program Directors incorporate into its *Suggested State Regulations for Control of Radiation* any relevant concepts from 10 CFR Part 35 that are not already integrated in those suggested regulations.

The CRCPD, comprising the radiation control programs in the 50 states (except Wyoming), the District of Columbia, and Puerto Rico, has developed and improved model state legislation for the regulation of all of ionizing radiation in medicine. The model legislation was first crafted by the Council of State Governments in 1962 and is revised periodically, most recently in 1991. On an ongoing basis the CRCPD has reviewed and revised its suggested state regulations in accordance with evolving scientific and technical information. Although the committee has determined that provisions in 10 CFR Part 35 need not be regulated at the federal level, it does encourage the CRCPD to undertake a systematic review and analysis of the concepts in Part 35 for possible adoption where relevant and appropriate.

C2. The committee recommends that all state legislatures enact enabling legislation to incorporate the regulation of reactor-generated byproducts into existing state regulatory programs.

Currently, almost all states have legislation governing the regulation of radiation, as noted in Chapter 3. These statutes include, to varying degrees, naturally occurring and accelerator-produced radionuclides and machine-produced radiation. If Congress acts in accordance with the committee's recommendation to transfer authority for regulation of reactor-generated radionuclides to the states, the states should either amend their existing radiation legislation to encompass reactor-generated byproduct material or promulgate new legislation that addresses byproduct material. States that did not include byproduct material in their existing regulatory programs, which means they would not license users within their borders, would effectively preclude those users from obtaining byproduct material from manufacturers, which (by other NRC regulations) require proof of licensure before selling the material.

Although the committee cannot guarantee that states will effectively regulate byproduct material, it believes that they will. This conclusion is based on the fact that states have effectively regulated naturally occurring and accelerator-produced radioactive material in the past and continue to do so. The CRCPD's *SSRCR* have been adopted, to varying degrees, by the majority of states. Additionally, the current NRC Agreement States already regulate byproduct material within their borders. There is no reason to think that any of these programs will be disbanded. Additionally, the JCAHO, the threat of malpractice suits, and the fear of adverse publicity in a competitive health care market all weigh against laxity that might lead to or not prevent adverse events.

C3. The committee recommends that the Conference of Radiation Control Program Directors and the states continually reevaluate their regulations and procedures pertaining to radiation medicine to ensure congruence with evolving scientific understanding of radiation bioeffects and to be in accord with advances in knowledge regarding benefits and risks related to medical and biomedical research uses of ionizing radiation in medicine.

As the CRCPD and the states fulfill their advisory, regulatory, and enforcement obligations, their revised recommendations, regulations, and procedures will reflect developments in scientific, technological, and regulatory knowledge. The committee wishes to stress the importance of promulgating and maintaining recommendations, regulations, and procedures in accord with state-of-the-art information. This is perhaps the most important function of the federal advisory agency envisioned in Alternative D described above—providing leadership and a level of assurance that the states are equipped with the most up-to-date information on the scientific and technical fronts.

CONCLUDING STATEMENT

The most important goals of regulation of radiation medicine are to assure the safety of patients, workers, and the public and to ensure that the benefits of regulating ionizing radiation will outweigh the risks. Whether the existing NRC regulatory system is the best approach for achieving this outcome was the focus of the committee's inquiry. Extensive discussion, throughout the study process, about the virtues and drawbacks of federal regulation, as contrasted with state regulation, took place. Ultimately, from a wide spectrum of possibilities, the committee identified Alternative D (described in Chapter 5), as its preferred strategy for addressing the issues originally set out in its charge. This approach removes regulatory authority from the NRC, shifts federal guidance to the DHHS, and delegates regulatory responsibility for byproduct material to the

states, with the proviso that only user sites and users that are licensed by the responsible state authority would have access to byproduct material.

With the articulation of this alternative and the recommendations set forth above, the committee believes that it has fulfilled its assigned task. This report offers to the nation an approach to the regulation of all ionizing radiation in medicine that will adequately protect the public's health and safety and assure broadest access of the public to the benefits of the full range of medical uses of ionizing radiation.

A

Committee Biographies

CHARLES E. PUTMAN, M.D., joined the faculty at Duke University Medical Center as chairman of the Department of Radiology in May 1977. He was named the first James B. Duke Professor of Radiology and Professor of Medicine in 1983. After serving as a department chair for eight years, he resigned his position to become vice chancellor of health affairs and dean of the School of Medicine. In 1987, he became vice provost for research and development and was subsequently appointed vice president of research administration and policy before becoming the executive vice president of administration. Currently he is senior vice president for research administration and policy. Dr. Putman is the author or coauthor of over 200 scientific manuscripts, abstracts, and chapters, principally dealing with pulmonary disease and thoracic imaging. He is editor or coeditor of six textbooks. He is a fellow of the American College of Physicians, the American College of Chest Physicians, the American College of Radiology, and the Royal Society of Medicine. He was elected a member of the Institute of Medicine in 1987.

ROBERT S. ADLER, J.D., is a professor of legal studies at the Kenan-Flagler School of Business at the University of North Carolina, Chapel Hill. He is also associate dean of the school's undergraduate program. He received a J.D. from the University of Michigan Law School in 1969. After graduation from law school, Professor Adler held a variety of jobs as an attorney, including service as a deputy attorney general for the Pennsylvania Justice Department, where he headed the Southwest Regional Office of the Pennsylvania Bureau of Consumer

Protection. He spent nine years as an attorney-adviser to two commissioners at the U.S. Consumer Product Safety Commission in Washington, D.C. Subsequently, he served as counsel to the Subcommittee on Health and the Environment of the Committee on Energy and Commerce of the U.S. House of Representatives. Professor Adler came to the University of North Carolina in 1987. At the Kenan-Flagler School of Business, he teaches courses in business law, business ethics, regulation, and negotiation. Professor Adler is currently the coordinator of the business ethics course in the MBA program. His research interests include product safety, product liability, regulation, commercial law, medical malpractice, and ethics. He has also been involved in numerous consumer protection and education activities for many years. He has been elected twice to the board of directors of Consumers Union, publisher of *Consumer Reports* magazine.

BYRON WM. BROWN, Jr., is a graduate of the University of Minnesota. He served as head of the graduate program in biostatistics in the Minnesota School of Public Health from 1965 to 1968, leaving to join the Stanford University faculty. There he has headed the Division of Biostatistics and, since 1988, has chaired the Department of Health Research and Policy. He is a past president of the Society for Clinical Trials and also of the Western North American Region of the International Biometrics Society. He is an elected member of the International Statistical Institute and the Institute of Medicine, and has served on various committees of the National Academy of Sciences and the Institute of Medicine. His interests are in the statistical aspects and methodology of quality control and biological assay, clinical trials, and health outcomes research.

JENNIFER DUNN BUCHOLTZ, R.N., M.S., O.C.N., is a clinical nurse specialist in the Division of Radiation Oncology at the Johns Hopkins Oncology Center in Baltimore, Maryland. She is also an adjunct faculty member of the University of Delaware, Department of Advanced Nursing Science, and associate faculty member, the Johns Hopkins School of Nursing. Ms. Bucholtz has been an active member of the Oncology Nursing Society and is former associate editor of both the *Oncology Nursing Forum* and *ONS Scan in Oncology Nursing*. She has authored numerous book chapters and articles on radiation therapy nursing and radiation safety for nurses, and is a frequent national lecturer on various oncology nursing topics. She earned her B.S. from Wayne State University College of Nursing and her M.S. from Boston University School of Nursing.

TIMOTHY J. CONLAN, Ph.D., is associate professor of government and politics at George Mason University, where he teaches courses on policymaking and intergovernmental relations. Prior to this, he served as assistant staff director of the Senate Subcommittee on Intergovernmental Relations and as a senior

analyst with the Advisory Commission on Intergovernmental Relations. He is the author of several books and articles on federalism and public policy, including *Federal Regulation of State and Local Governments: The Mixed Record of the 1980s, Taxing Choices: The Politics of Tax Reform*, and *New Federalism: Intergovernmental Reform from Nixon to Reagan*. Dr. Conlan received his A.B. degree in political science from the University of Chicago and his Ph.D. in government from Harvard University.

BARBARA Y. CROFT, Ph.D., is an associate professor in the Department of Radiology at the University of Virginia. She has been on the University of Virginia faculty for over 25 years. She has been a member of advisory panels to the National Institutes of Health (NIH), the National Science Foundation (NSF), the Food and Drug Administration, and the Department of Energy. Dr. Croft is a past president of the Society of Nuclear Medicine and a fellow of the American College of Nuclear Physicians. She is a member of the board of the Education and Research Foundation of the Society of Nuclear Medicine. She maintains an active interest in nuclear medicine reimbursement issues and in practice and protocol guidelines for nuclear medicine procedures.

Dr. Croft has served as an expert for the International Atomic Energy Agency in missions to numerous countries. She has authored a book on single photon emission computed tomography and has coauthored a text in radiopharmacy. She has written on renal and pulmonary internal dosimetry and iodine radiation safety issues. Dr. Croft received her B.S. from Swarthmore College and her M.S. and Ph.D. from the Johns Hopkins University.

SISTER ROSEMARY DONLEY, R.N., Ph.D., F.A.A.N., is executive vice president for the Catholic University of America. Prior to assuming her present position, she was dean of nursing at Catholic University. In 1977, Sister Rosemary was elected to be a Robert Wood Johnson Health Policy Fellow. She is a fellow in the American Academy of Nursing and is a member of the Institute of Medicine. She is a past president of the National League for Nursing and of Sigma Theta Tau International Honor Society of Nursing, and a past senior editor of *Image: The Journal of Nursing Scholarship*. She serves on many civic and health advisory boards, which include the Secretary of Health and Human Service's Commission on Nursing. She has been awarded six honorary degrees and is the author of 60 chapters and articles. Her major interests are health policy and decisionmaking.

DAVID S. GOODEN, Ph.D., J.D., is the director of biomedical physics at Saint Francis Hospital in Tulsa. For almost 26 years he has served Saint Francis Hospital as radiation safety officer and radiological physicist for diagnostic x-ray, radiation therapy, and nuclear medicine. Dr. Gooden is chairman of the Radiation Advisory Council for Oklahoma's Department of Environmental Quality.

He has B.S. and M.S. degrees in physics from Emory University, a Ph.D. in nuclear reactor engineering from the University of Missouri, and a J.D. from Tulsa University. Dr. Gooden has provided radiation safety consultation in many areas, including health care, veterinary medicine, nuclear reactors, electric utilities, universities, industrial radiography, waste management, scrap metal salvage, foundries, and oil and gas production. He has published works in the areas of medical physics and the legal aspects of radiation injury. Dr. Gooden is certified by the American Board of Health Physics (health physics), the American Board of Radiology (radiological physics), and the American Board of Medical Physics (radiation oncology physics).

WILLIAM R. HENDEE, Ph.D., is senior associate dean and vice president of the Medical College of Wisconsin and dean of the college's graduate school. He holds academic appointments as professor of radiology, radiation oncology, biophysics, and bioethics, and is an adjunct professor of biomedical engineering at Marquette University. He is director of the college's Health Information Technology Center and executive vice president of the Medical College of Wisconsin Research Foundation. He has served on advisory panels for the National Cancer Institute, Environmental Protection Agency (EPA), Department of Labor, National Institute of Occupational Safety and Health, Veterans Administration, and Food and Drug Administration. Prior to joining the Medical College of Wisconsin, Dr. Hendee was vice president at the American Medical Association. For two decades he was on the faculty of the University of Colorado School of Medicine, where he served for eight years as professor and chairman of the Department of Radiology. Dr. Hendee is the author or coauthor of over 350 scientific papers and the author or editor of over 20 books, including *Medical Radiation Physics* (three editions); *Health Effects of Exposure to Low Level Ionizing Radiation* (two editions); *Radiation Therapy Physics* (two editions); *Perception of Visual Information; Digital Imaging*; and *The Health of Adolescents* . Dr. Hendee received his Ph.D. in physics from the University of Texas.

DAVID E. KUHL, M.D., is a professor of internal medicine and radiology at the University of Michigan School of Medicine. He received an A.B. in physics from Temple University in 1951 and an M.D. from the University of Pennsylvania in 1955. His research interests include local cerebral physiology as determined by emission computed tomography (PET and SPECT) using radioactive tracers. He has served on advisory panels for the U.S. Atomic Energy Commission and the Nuclear Regulatory Commission, the National Academy of Sciences, the National Institutes of Health, the Senior Fulbright Hayes Program, Los Alamos Scientific Laboratory, Brookhaven National Laboratory, the National Cancer Institute, Oak Ridge Associated Universities, the California Medical Association, the Department of Energy (DOE), and the Max Planck Institute

for Neurological Research. Dr. Kuhl was elected to the Institute of Medicine in 1989.

LESTER B. LAVE, Ph.D., is the Harry B. and James H. Higgins Professor of Economics and Finance and University Professor at the Graduate School of Industrial Administration, Carnegie-Mellon University. He is also professor of engineering and public policy in the School of Engineering and professor of urban and public affairs in the Heinz School of Public Policy. He earned a B.A. from Reed College in 1960 and a Ph.D from Harvard University in 1963. From 1968 to 1972 he was a senior fellow at the Brookings Institution. He has also been an adjunct professor at the Georgetown University Law School and the Graduate School of Public Health, University of Pittsburgh, and was a visiting assistant professor in the Department of Economics at Northwestern University. Dr. Lave has served on some two dozen committees of the Institute of Medicine, National Research Council, and National Academy of Sciences since he joined the Executive Committee of the Assembly of Behavioral and Social Sciences (ABASS) in 1971. During 1975–1976, he was acting chair of ABASS. He was elected to the Institution of Medicine in 1981. He has acted as a consultant to numerous federal government agencies, including Department of Justice, DOE, Department of Defense (DOD), Department of Transportation, Department of Health and Human Services, EPA, and Occupational Safety and Health Administration (OSHA), and to many corporations and trade associations, such as Xerox, General Motors, and the American Petroleum Institute. Dr. Lave has received research grants from NSF, NIH, National Institute for Mental Health, EPA, OSHA, DOE, DOD, the R.K. Mellon Charitable Trusts, the Heinz Foundation, the Scaife Foundation, the Sloan Foundation, and the National Safety Council.

THEODORE L. PHILLIPS, M.D., has served as professor and chairman of the department of radiation oncology at the University of California, San Francisco (UCSF) since 1977, and was professor and chief of the Radiation Therapy Section of the Department of Radiology at UCSF from 1970 to 1977. He is a research physician at Lawrence Berkeley Laboratory and a research associate of the Cancer Research Institute and the Laboratory of Radiobiology at UCSF. He has been president of the American Society for Therapeutic Radiology and Oncology, the Radiation Research Society, and the North American Hyperthermia Society. Dr. Phillips was awarded the Janeway Medal by the American Radium Society, the Gold Medal by the American Society for Therapeutic Radiology and Oncology, and the Chester Stock Medal of Memorial Sloan Kettering Cancer Center in 1993. He was elected to the Institute of Medicine in 1994. Dr. Phillips has written over 275 peer-reviewed articles and has contributed numerous meeting summaries, editorials, and abstracts. He received his Sc.B. from Dickinson College and his M.D. from the University of Pennsylvania.

MARCIA O. STEVIC, Ph.D., R.N., has 30 years of health care experience and expertise in quality and outcomes measurement. She is currently a health outcomes researcher at the Health Services Advisory Group in Phoenix, Arizona. While serving as director of quality research at the Cleveland Clinic from 1989 to 1994, she designed and implemented outcomes projects in acute and chronic medical and surgical conditions. In 1985, Dr. Stevic served as an intern at the Health Care Financing Administration, and since then she has been active in national and international health policy initiatives; has participated on the Uniform Needs Assessment Instrument Panel; sits on the American Medical Review Research Center Board; is chair of the Development of Review Criteria for Urinary Incontinence Panel; serves on the Agency for Health Care Policy and Research's workgroup to write the methodology for evaluating guidelines, measuring performance, and setting standards; and serves on the editorial advisory board of the *International Journal of Quality Assurance*. Dr. Stevic holds a B.S. and M.S. in nursing and a Ph.D. in medical sociology from the State University of New York at Buffalo.

JOHN C. VILLFORTH, is president of the Food and Drug Law Institute (1990–present). The Institute is a nonprofit educational organization dedicated to promoting an understanding of the laws and regulations as administered by the Food and Drug Administration. Mr. Villforth was formerly director of the Bureau of Radiological Health (1969–1982) and director of the Center for Devices and Radiological Health at the Food and Drug Administration (1982–1990). He was responsible for developing and overseeing nationwide programs to reduce population exposure to radiation emitted from medical and consumer products and to ensure the safety and effectiveness of medical devices. Assistant Surgeon General Villforth was also appointed chief engineer in the U.S. Public Health Service (1985–1990). Mr. Villforth received his B.S. and M.S. in sanitary engineering from Pennsylvania State University, as well as an M.S. in physics from Vanderbilt University.

J. FRANK WILSON, M.D., F.A.C.R., is professor and chairman of the Department of Radiation Oncology and acting director of the cancer center at the Medical College of Wisconsin. He has served as a senior investigator in the radiation branch of the National Cancer Institute and has held faculty positions at Penrose Cancer Hospital and the College of Medicine of the University of Paris. Dr. Wilson is board certified in therapeutic radiology and is a fellow of the American College of Radiology. His clinical interests include developmental aspects of brachytherapy, and he has coauthored the standard textbooks in this field.

Dr. Wilson is past chairman of the board and president of the American Society for Therapeutic Radiology and Oncology and is on the board of directors of the National Coalition for Cancer Research. He serves on the executive committee

of the International Society of Radiation Oncology and has also been on the executive committee of the American Radium Society. He serves on the editorial boards of numerous peer-reviewed journals and is senior associate editor for brachytherapy for the *International Journal of Radiation Oncology, Biology, and Physics*. He is an authority on the treatment of breast cancer and is the chair of the Breast Committee of the Patterns of Care Study currently being conducted by the American College of Radiology.

BARRY L. ZARET, M.D., is currently the Robert W. Berliner Professor of Medicine and professor of diagnostic radiology at the Yale University School of Medicine. He has been chief of cardiovascular medicine at Yale since 1978 and was recently appointed to the position of associate chair for clinical affairs of the Department of Internal Medicine. Dr. Zaret received a B.S. in chemistry from Queens College, City University of New York, and an M.D. from New York University School of Medicine. He obtained postgraduate training in medicine and cardiology at Bellevue Hospital and Johns Hopkins. He has published more than 250 articles, chapters, and reviews. In addition to membership in several prominent professional societies, including American Society Clinical Investigators, America College of Cardiology, the Association of University Cardiologists, and the Association of Professors of Cardiology, Dr. Zaret is editor-in chief of the *Journal of Nuclear Cardiology* and was associate editor of the *Yearbook of Nuclear Medicine* from 1980 to 1995. He is a past president of the Association of Professors of Cardiology. He has been active in research and clinical performance of nuclear cardiology since 1970.

COMMITTEE STAFF

KATE-LOUISE GOTTFRIED, J.D., M.S.P.H. is study director of the 24 month study evaluating the Medical Use Program of the U.S. Nuclear Regulatory Commission. She joined the IOM staff in February 1994. Before joining IOM, Kate-Louise spent over ten years working in the health care field, primarily in academic health care centers. Her initial training in health administration led to a series of administrative positions and subsequent legal training resulted in an opportunity to practice health law at a firm in New Jersey. Most recently she was the director of risk management and assistant general counsel at a large county hospital in New York. She earned her B.A. in anthropology from the University of Michigan, her M.S.P.H. from the University of North Carolina, and her J.D. from Rutgers School of Law.

GARY PENN, J.D. is the research associate on this study. Prior to joining the IOM staff in December 1994, he studied health law at the University of Houston. As part of those studies, Gary spent several months at the Council of

Europe in Strasbourg, France, working on a draft Convention on Bioethics. He received a degree in East Asian Studies from Princeton University and earned his J.D. from Hastings College of Law in San Francisco.

B

Abbreviations and Acronyms

ASSOCIATIONS AND SOCIETIES

ACR	American College of Radiology
BEAR	Committee on Biologic Effects of Atomic Radiation (NAS/NRC)
BEIR	Committee on the Biological Effects of Ionizing Radiation (NAS/NRC)
CRCPD	Conference of Radiation Control Program Directors
IOM	Institute of Medicine
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
NAS/NRC	National Academy of Sciences/National Research Council
NCRP	National Council on Radiation Protection
USP	United States Pharmacopoeia

FEDERAL GOVERNMENT PROGRAMS AND AGENCIES

ACMUI	Advisory Committee on the Medical Uses of Isotopes
AEC	Atomic Energy Commission
AEOD	Office for Analysis and Evaluation of Operational Data (NRC)
BMD	Bureau of Medical Devices
BRH	Bureau of Radiological Health
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CIRRPC	Committee on Interagency Radiation Research and Policy Coordination
DHHS	Department of Health, Education and Welfare (now DHHS)

DHHS	Department of Health and Human Services
DOD	Department of Defense
DOE	Department of Energy
DOT	Department of Transportation
EPA	Environmental Protection Agency
ERDA	Energy Research and Development Agency
FDA	Food and Drug Administration
FR	Federal Register
FRC	Federal Radiation Council
GAO	General Accounting Office
HCFA	Health Care Financing Administration
JCAE	Joint Committee on Atomic Energy
NRC	Nuclear Regulatory Commission
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
PHS	Public Health Service
RPC	Radiation Policy Council
VA	Department of Veterans Affairs

INTERNATIONAL ORGANIZATIONS

ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation

LEGISLATION AND EXECUTIVE ORDERS

AEA	Atomic Energy Act of 1954, as Amended
ERA	Energy Reorganization Act of 1974
MQSA	Mammography Quality Standards Act of 1992
RCHS	Radiation Control for Health Safety Act of 1968
SMDA	Safe Medical Device Act of 1991

MISCELLANEOUS

ADE	Adverse drug event
ALAP	As low as practicable
ALARA	As low as reasonably achievable
ALI	Annual limit on intake
BRC	Below regulatory concern
CABG	Coronary artery bypass graft
CT	Computed tomography

DIS	Decay in storage
DREF	Dose rate effectiveness factor
EDE	Effective dose equivalent
ESK	Entrance skin air kerma
FTE	Full-time equivalent
FY	Fiscal year
GI	Gastrointestinal
HDR	High dose rate
IORT	Intraoperative radiation therapy
LDR	Low dose rate
MPD	Maximum permissible dose
MRI	Magnetic resonance imaging
NARM	Naturally occurring and accelerator-produced radioactive material
PET	Positron emission tomography
POCS	Patterns of care study
QA	Quality assurance
QM	Quality management
RPG	Radiation protection guide
RSO	Radiation safety officer
SPECT	Single photon emission computed tomography
SRS	Stereotactic radiosurgery
SSRCR	*Suggested State Regulations for the Control of Radiation*
UGI	Upper gastrointestinal

C

Glossary

Ablation means removal or destruction.

Absorbed dose is a measure of the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray and the rad.

Absorption of radiation is the process through which radiation deposits some or all of its energy as it passes through matter.

Activity— see **Radioactivity**.

Acute radiation injury is an injury that manifests itself within the first several weeks after exposure to radiation.

Angiography is the study of blood vessels, usually using x-rays and a pharmaceutical called a **contrast agent**.

Anode is a positively charged electrode. Negative ions are attracted to anodes.

Atoms are the smallest particles with which an element can enter into a chemical reaction. Atoms are characterized by an atomic number describing their proton number and elemental identity and by an atomic mass number that varies according to the total number of protons and neutrons in the atom.

Attenuation of radiation is the reduction in intensity that occurs as radiation interacts with matter. Attenuation occurs through a combination of scattering and absorption.

Authorized user means an individual who is identified as an authorized user on a license for the medical use of radioactive material.

Background radiation is naturally occurring radioactivity and radiation caused by cosmic rays.

Beta particles are electrons (beta-minus) or positrons (beta-plus) that are emitted by the nucleus of a radioactive atom.

Biological half-life is the time required for the body or an organ system to eliminate half of the dose of an administered compound.

Brachytherapy is radiation therapy using sealed radioactive sources placed inside or on the surface of the patient. These may be intercavitary (within body cavities), interstitial (within tissues), after loaded (i.e., put in after tubes, holders, etc., to contain them are placed in the patient), high dose rate (i.e., using large amounts of radioactivity to get the maximum effect in a short time), or low dose rate.

Byproduct material is defined under the Atomic Energy Act of 1954, 42 SC 2014 Sec. 11(e) to mean: (1) any radioactive material (except special nuclear material) produced during the process of producing or utilizing special nuclear material, and (2) the tailings or wastes produced during the extraction or concentration of uranium or thorium from any ore. This latter category is of no relevance in medicine.

Cancer is the commonly used term for any malignant neoplasm.

Chain reaction denotes any process in which some of the reaction products become reaction raw materials. In particular, nuclear reactors consume and produce neutrons simultaneously as nuclei fission in a chain reaction.

Chemotherapy is the treatment of disease with chemical compounds. The term is generally used in connection with the use of chemical for treatment for malignant disease.

Committed effective dose equivalent is the sum of the products of the applicable weighting factors for each of the body organs or tissues that are irradiated multiplied by the committed dose equivalent to that area.

Computed tomography (CT), or x-ray transmission computed tomography, is an x-ray technique in which the x-ray tube and possibly the detector are rotated around the patient; the detected signal produced by transmitted x-rays is processed by a computer to create transaxial images of x-ray attenuation in the patient. The technique enhances contrast by decreasing the contribution of scattered x-rays to the image.

Contamination, radioactive, is the deposition of radioactive material where its presence is not desired.

Contrast agents are pharmaceuticals used to enhance the distinction of bright and dark tones of images by changing some property in the patient. Many x-ray contrast agents contain iodine or barium, which attenuate x-rays more than the elements in the body.

Contrast of images refers to the distinction between bright and darktones.

Cosmic rays are radiation that originates outside the earth's atmosphere.

Curie (Ci) is the unit of radioactivity used in the older literature; it is equal to 3.7×10^{10} disintegrations per second. The Système Internationale d'Unités (SI) unit supplanting the curie is the becquerel (Bq), where 1 Bq = 1 disintegration per second.

Cyclotron is a device used for accelerating charged particles in a spiral path to create high-energy particles.

Decay, radioactive, is the disintegration of the nucleus of an atom with the emission of radiation, representing a release of mass, energy, or both. This process may also be referred to as nuclear or radioactive disintegration.

Decay in storage (DIS) means allowing radioactive materials with short half-lives to decay to background levels in storage facilities, then disposing of them by conventional waste disposal methods.

Deterministic (nonstochastic) means that the intensity of a radiobiologic effect is related to the amount of exposure. In such an effect there is believed to be a threshold below which the effect is not seen.

Dosage is the amount of a material administered. Dosages may be incorrectly referred to as doses.

Dose is the energy delivered to the body by radiation. It is a generic term encompassing absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. (See 10 CFR 20.1003.)

Dose equivalent is a concept for modifying the absorbed dose to take into account the body part exposed, the dose rate, the age of the exposed person, and the type of radiation involved, such as photons, alpha, or other heavy or multiply charged particles, neutrons of unknown energy, or high-energy protons. The dose equivalent is the product of the absorbed dose in tissue, the quality factor for the radiation, and all other necessary modifying factors for the anatomic location. The unit for dose equivalent is the sievert.

Dose rate is the rate at which radiation energy is delivered.

Dosimetrist is an individual who calculates radiation doses, usually for radiation therapy.

Dosimetry is the measurement of radiation doses.

Effective dose equivalent (EDE) is the sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the organs or tissues that are irradiated. Its purpose is to put radiation doses to different anatomic locations on an equivalent basis for creating estimates of doses to populations.

Electrons are negatively charged particles that surround the nucleus of an atom and determine its chemical properties. The mass of an electron is 1/1,835th the mass of a proton.

Element is a pure substance consisting of atoms of the same atomic number. The atoms will contain the same number of protons, but a naturally occurring element may be a mixture of isotopes —nuclei with different numbers of neutrons.

Epilation is the loss of hair, either temporary or permanent.

Error is a term used in several ways. In the narrow sense, it means a mistake or incorrect conclusion. In the broader sense, "error" is used as a synonym for "uncertainty" in statistics; thus one talks about the "standard error of the mean," which reflects a statistical uncertainty.

Erythema is a reddening of the skin resulting from radiation exposure. At one time it was used as a measure of the radiation dose received.

External dose means that portion of the dose equivalent received from radiation sources outside of the body.

Extrapolation means making an estimate of an effect from data acquired beyond the range of interest. Its opposite is interpolation, in which estimates are made of values between acquired data points.

Fission means "splitting"; nuclear fission is the splitting of atoms into two or more parts of significant mass. Large amounts of energy, representing the difference in binding energy of the particles in the original nucleus and in the final particles, are released. Nuclear fission is the energy-producing mechanism exploited in the nuclear power reactor.

Fluoroscopy is x-ray imaging of changes in the body or the distribution of a contrast agent in real time.

Gamma rays are short-wavelength electromagnetic radiation (photons) that is emitted from the nucleus.

Gray (Gy) is an SI unit of absorbed radiation dose, equal to an imparted energy of 1 joule per kilogram of matter. The older unit was the rad; 100 rads = 1 Gy.

Half-life is the time it takes for half of the substance under consideration to disappear. If the value is unqualified, for radioactive materials, half-life refers to the physical half-life, which is a property of the decay of the radionuclide under consideration.

Interstitial means "between cells."

Ion means a charged atom, either positive or negative.

Ionizing radiation, in the broadest sense, is any radiation that removes electrons from atoms (or molecules). This radiation comes from natural sources, such as cosmic radiation or naturally occurring elements such as radium, uranium, thorium, and radon. It also comes from anthropogenic (human-made) materials, such as those produced in a nuclear reactor. Finally, the radiation comes from machines such as x-rays and fluoroscopes. Ionizing radiation in medicine for both diagnostic and therapeutic purposes is derived from a number of sources: (1) reactor-generated byproduct material and special nuclear materials produced in reactors, naturally occurring and accelerator-produced radioactive materials, and (3) x-ray machines and particle accelerators.

Isotopes are a group of atoms that have the same proton number but different numbers of neutrons. Because the proton number determines the elemental identity, a discussion of isotopes is properly a discussion of different nuclides of the same element. The word "isotope" has been improperly used over the years to mean radioactive material or radionuclides.

Linear accelerator is a device for accelerating a charged particle. It is commonly used in radiation therapy.

Late radiation injury refers to radiation-induced cancer diagnosed a few to many years after exposure.

Linear means a straight line or a direct relation between a dependent and an independent variable.

Linear, no-threshold model, means the extrapolation of late and genetic radiation effects to low dose levels in a linear or straight-line fashion from data obtained at higher doses. It is presumed to define the upper limit of estimated effects.

Magnetic resonance imaging (MRI) is the production of images from small signals emitted by hydrogen nuclei when, in a magnetic field, they return from an excited state to the ground state. Ionizing radiation is not used in MRI.

Malignant connotes a tumor that is capable of metastasis or spreading to remote anatomic sites.

Manhattan Project was the code name for the World War II effort to create a sustained fission reaction and an explosive device from that reaction. The resources and effort concentrated in this project rapidly developed much of what we know about radioactive materials today.

Maximum permissible dose (MPD) is the maximum absorbed dose per unit time allowed to a particular type of individual, such as a member of the public or a radiation worker. There is no MPD for patients.

Medical institution means an organization in which several medical disciplines are practiced (this is the Nuclear Regulatory Commission's (NRC) definition). In the broader usage, medical institution and hospital are synonyms. A hospital is a place where high-intensity procedures, such as surgery with anesthesia, are performed. This is in contrast to a physician's office, where only low-intensity procedures might be performed, or to a free-standing imaging center, where only imaging might be performed.

Metabolism is the sum of all the physical and biological processes that produce and maintain a living organism.

Metastasis means the spread of malignant cells beyond their original anatomic site.

Microcurie means 1/1 millionth of a curie, or 3.7×10^4 disintegrations per second.

Milliroentgen means 1/1,000th of a roentgen, or 0.001 R.

Misadministration means, in common parlance, the usage of the wrong pharmaceutical or treatment or the wrong amount, on the wrong patient, or at the wrong time. For the meaning that the NRC uses, see 10 CFR 35.2; it is noted that the definition has changed over time, so it and any statistics on misadministrations involving byproduct materials should be related to the definition in force at the time of reporting.

NARM	stands for naturally occurring and accelerator-produced radioactive material and stands in direct opposition to reactor-generated byproduct material. NARM and x-rays are not regulated under the Atomic Energy Act.
Naturally occurring radioactive material	are those materials that occur naturally in the universe and that spontaneously decay to emit radiation. The first of these to be exploited medically for its radioactive properties was radium.
Neutron	is a neutral nuclear particle of mass almost equal to that of the proton.
Nondeterministic (stochastic)	is applied to effects in which the likelihood of an event, but not the seriousness or intensity, varies with the amount of exposure.
Nuclear medicine	is a branch of medicine that uses very small (tracer) amounts of pharmaceuticals labeled with radioactive materials for diagnosis and therapy. Much of the diagnosis is accomplished by imaging the distribution of the radiopharmaceutical within the body; body functions and metabolism may therefore be studied without disruption. Radiation therapy with these unsealed sources may be targeted to particular tissues.
Nuclear reactor	is a device in which a nuclear fission reaction may be self-sustaining. In medicine, nuclear reactors may be used to create radioactive materials for administration to patients for both diagnostic and therapeutic purposes and to produce teletherapy sources. A reactor may also be used as a source for thermal or epithermal neutrons to irradiate a boron compound in a patient's tumor so that it becomes a source of ionizing radiation in the patient. This is referred to as boron-neutron capture therapy.
Nuclide	denotes any nucleus and its orbital electrons. It is a synonym for atom or element, but often is used when a particular mass number is being discussed.
Occupational exposure	(using the NRC's definition of occupational dose) means radiation exposure to an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation. It does not include background radiation, medical radiation exposure, exposure during voluntary participation in medical experiments, or as a member of the general public. (See 10 CFR 20.1003.)
Oncology	is the study of the genesis and proliferation of malignant tissue and refers to the medical discipline responsible for the diagnosis and treatment of patients with malignancies.
Palliative radiation therapy	means the use of radiation to contribute to a patient's comfort and decrease pain, but not necessarily to prolong life or "cure" a disease.

Particle accelerators produce accelerated charged particles that range from electrons to heavy protons and ions such as carbon and argon. These particles may be used directly or directed onto a target to produce x-rays or fast neutrons. Particle accelerators are used to create radioactive materials for later administration to patients, mostly for diagnostic purposes, and to irradiate patients directly for treatment of malignancies. The accelerators may be betatrons, cyclotrons, linear accelerators, or synchrotrons, named for selected characteristics of their design.

Person-sievert, or person-Sv, is a unit that represents the sum of the number of people exposed to radiation multiplied by their effective dose equivalent.

Photon denotes a quantity of electromagnetic energy. Photons have no mass but do have momentum. Visible light, gamma rays, and x-rays are all photons.

Physical half-life is the time required for half of a radioactive material to decay.

Physician means a medical doctor or doctor of osteopathy licensed by a state or other authorities to prescribe drug treatments in the practice of medicine.

Positron is a particle having a mass equal to that of the electron and a positive charge. The positron is anti-matter; when it interacts with an electron, they annihilate and photons are formed, which carry away the energy. The positron is also called a beta-plus particle, since it is like the beta-minus particle in origin. Positrons may be emitted in the radioactive decay process of radionuclides that contain excess protons; medically useful positron emitters include carbon-11, oxygen-13, nitrogen-15, and fluorine-18.

Positron emission tomography (PET) is a tomographic technique in which detectors surround a patient who has been made radioactive with a positron-emitting radiopharmaceutical; the information from the detector is processed by the computer to create transaxial images of the distribution of the radiopharmaceutical within the patient.

Rad is a unit of radiation absorbed dose. One rad is equal to 100 ergs deposited per gram of substance. The gray is the equivalent SI unit; 1 Gy = 100 rads.

Radiation oncology is the study and treatment of malignant disease with radiation.

Radiation therapy is the treatment of malignant disease with radiation. It is essentially a synonym for radiation oncology.

Radioactivity means the spontaneous disintegration of a nucleus in which alpha, beta, or gamma radiation may be emitted.

Radioisotope— see **Isotope.**

Radionuclide means a nuclide that disintegrates, thus emitting radiation.

Radiopharmaceutical is a pharmaceutical containing radioactivity. Radiopharmaceuticals may be made in a user's laboratory by combining radioactive materials with nonradioactive kits or by cyclotron production and subsequent formulation of materials with short half-lives; radiopharmaceuticals may also be purchased from commercial radiopharmacies or manufacturers.

Radiosensitivity means that some cells are relatively more sensitive to radiation than others.

Recordable event means, according to the NRC (10 CFR 35.2) an event that is less serious than a misadministration (see **Misadministration**), but involving a dosage other than that prescribed of sodium iodide I-131 or I-125 or a therapeutic radiopharmaceutical, or of radiation from a brachytherapy or teletherapy treatment.

Rem is a unit of dose equivalent. It is equal to the dose in rads multiplied by a quality factor for the particular type of radiation. The SI unit for dose equivalents is the sievert (Sv); 1 Sv = 100 rem.

Risk coefficient is defined in terms of fatalities per person-Sv and allows a comparison between the risks of exposure to radiation and other risks.

Roentgen is a unit of x- or gamma-radiation exposure such that absorption by 1 cubic centimeter of air produces an electrical charge of 1 electrostatic unit (esu). There is no SI equivalent to this unit, as its use is expected to disappear.

Roentgen equivalent man (rem) is a unit of human biologic dose as a result of exposure to one or more types of ionizing radiation. It is equal to the absorbed dose in rads times the Relative Biological Effectiveness of the radiation in question.

Scanner is a device used to detect x-rays or gamma radiation from a volume of tissue. The word is used in connection with nuclear medicine imaging and CT imaging. Originally it connoted a detector device that went back and forth to cover an area, but is now used colloquially for several kinds of instruments.

Scattering is the loss of radiation from a beam by deflection by nuclei or electrons. Generally scattered radiation has a lower energy than the original beam.

Scintillation counter combines an absorbing phosphor, a photomultiplier tube, a sample holder, and associated devices and circuits needed to count the light emissions created as the result of absorption of ionizing radiation in the phosphor. If the absorbing phosphor is liquid and the sample being counted is dissolved in the liquid, the counter is a "liquid scintillation counter" and may detect beta and gamma rays.

Sealed source means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the contents; the NRC defines sealed sources in terms of encapsulated byproduct material.

Sievert (Sv) is the SI unit for dose equivalent. It is equal to 100 rem.

Stable isotopes are those isotopes of an element that do not disintegrate and are thus not radioactive. Stable isotopes may be used in magnetic resonance imaging or in tracer methods that use mass spectrometry for detection.

Stochastic— see **Nondeterministic.**

Teletherapy is radiation therapy by means of an external beam of radiation. The source is commonly a cobalt-60 irradiator or a linear or other accelerator.

Transmutation means changing one element into another. This occurs in radioactive decay whenever a charged particle such as an alpha or beta particle is emitted.

Weighting factor is a way of taking into account the particular anatomic area irradiated in a calculation involving the equivalent dose to the whole body. The weighting factor for an organ or tissue is the proportion of the risk of stochastic effects resulting from irradiation of that area to the total risk of stochastic effects when the whole body is irradiated. (See **Committed effective dose equivalent.**)

Worker or employee in the radiation industry is an individual who may be exposed as a result of his or her occupation.

X-rays are short-wavelength electromagnetic radiations (photons) that emanate from energy changes in electronic shells.

X-ray machines are used in medicine for both diagnostic and therapeutic purposes. In an x-ray machine, a beam of x-rays is generated when a stream of electrons hits an anode target; the beam is directed by collimation toward the field to be irradiated. After being attenuated by passing through an object such as a patient, x-rays are detected by a screen–film combination inside a cassette or by a fluorescent screen in an image-intensifier tube. The screen–film combination yields a film for diagnosis by a physician; the image-intensifier tube signal is fed into a video system for immediate viewing, as in fluoroscopy. X-rays may be used therapeutically to treat cancer.

D

Selected Sections of the United States Code of Federal Regulations[1]

[1] 10 CFR Part 20 (Standards for Protection Against Radiation) and 10 CFR Part 35 (Medical Use of Byproduct Material)

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55071, Nov. 24, 1992]

§ 19.31 Application for exemptions

The Commission may upon application by any licensee or upon its owninitiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not result in undue hazard to life or property.

§ 19.32 Discrimination prohibited

No person shall on the ground of sex be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity licensed by the Nuclear Regulatory Commission. This provision will be enforced through agency provisions and rules similar to those already established, with respect to racial and other discrimination, under title VI of the Civil Rights Act of 1964. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminate.

[40 FR 8783, Mar. 3, 1975]

§ 19.40 Criminal penalties

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 19 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 19 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 19.1, 19.2, 19.3, 19.4,19.5, 19.8, 19.16, 19.17, 19.18, 19.30, 19.31, and 19.40.

[57 FR 55071, Nov. 24, 1992]

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

Subpart A—General Provisions

Subpart B—Radiation Protection Programs

Subpart C—Occupational Dose Limits

Subpart D—Radiation Dose Limits for Individual Members of the Public

Subpart E—(Reserved)

Subpart F—Surveys and Moniforing

Subpart G—Control of Exposure From External Sources in Restricted Areas

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended (2 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Subpart A—General Provisions

SOURCE: 56 FR 23391, May 21, 1991, unless otherwise noted.

§ 20.1001 Purpose

(a) The regulations in this part establish standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the Nuclear Regulatory Commission. These regulations are issued under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

(b) It is the purpose of the regulations in this part to control the receipt, possession, use, transfer, and disposal of licensed material by

any licensee in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the regulations in this part. However, nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

§ 20.1002 Scope

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under parts 30 through 36, 39, 40, 50, 60, 61, 70, or 72 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

[56 FR 23391, May 21, 1991, as amended at 58 FR 7736, Feb. 9, 1993]

§ 20.1003 Definitions

As used in this part:

Absorbed dose means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

Act means the Atomic Energy Act of 1954 (42 U.S.C. 2011 *et seq.*), as amended.

Activity is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

Adult means an individual 18 or more years of age.

Airborne radioactive material means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

Airborne radioactivity area means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations—

(1) In excess of the derived air concentrations (DACs) specified in appendix B, to §§ 20.1001–20.2401, or

(2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

ALARA (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

Annual limit on intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of appendix B to §§ 20.1001–20.2401).

Background radiation means radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material) and global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include radiation from source, byproduct, or special nuclear materials regulated by the Commission.

Bioassay (radiobioassay) means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute ''byproduct material'' within this definition.

Class (or *lung class* or *inhalation class*) means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D (Days) of less than 10 days, for Class W (Weeks) from 10 to 100 days, and for Class Y (Years) of greater than 100 days.

Collective dose is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Committed dose equivalent ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

Committed effective dose equivalent ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma W_T H_{T,50}$).

Controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

Declared pregnant woman means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

Deep-dose equivalent (H_d), which applies to external whole body exposure, is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2).

Department means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95–91, 91 Stat. 565, 42 U.S.C. 7101 *et seq*.) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers, and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c), and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93–438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95–91, 91 Stat 565 at 577–578, 42 U.S.C. 7151).

Derived air concentration (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. DAC values are given in Table 1, Column 3, of appendix B to §§ 20.1001–20.2401.

Derived air concentration-hour (DAC-hour) is the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

Dose or *radiation dose* is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of this section.

Dose equivalent (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

Dosimetry processor means an individual or organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

Effective dose equivalent (H_E) is the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factors (WT) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma W_T H_T$).

Embryo/fetus means the developing human organism from conception until the time of birth.

Entrance or access point means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

Exposure means being exposed to ionizing radiation or to radioactive material.

External dose means that portion of the dose equivalent received from radiation sources outside the body.

Extremity means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

Eye dose equivalent applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

Generally applicable environmental radiation standards means standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

Government agency means any executive department, commission, independent establishment, corporation wholly or partly owned by the United States of America, which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

Gray [See § 20.1004].

High radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Individual means any human being.

Individual monitoring means—

(1) The assessment of dose equivalent by the use of devices designed to be worn by an individual:

(2) The assessment of committed effective dose equivalent by bioassay (see *Bioassay*) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

(3) The assessment of dose equivalent by the use of survey data.

Individual Monitoring Devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

Internal dose means that portion of the dose equivalent received from radioactive material taken into the body.

License means a license issued under the regulations in parts 30 through 36, 39, 40, 50, 60, 61, 70, or 72 of this chapter.

Licensed material means source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the Commission.

Licensee means the holder of a license. *Limits* (dose limits) means the permissible upper bounds of radiation doses.

Lost or missing licensed material means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

Member of the public means an individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

Minor means an individual less than 18 years of age.

Monitoring (radiation monitoring, radiation protection monitoring) means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

Nonstochastic effect means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

NRC means the Nuclear Regulatory Commission or its duly authorized representatives.

Occupational dose means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the general public.

Person means—

(1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department of Energy (except that the Department shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity: and

(2) Any legal successor, representative, agent, or agency of the foregoing.

Planned special exposure means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

Public dose means the dose received by a member of the public from exposure to radiation and to radioactive material released by a licensee, or to another source of radiation either within a licensee's controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

Quality Factor (Q) means the modifying factor (listed in tables 1004(b).1 and 1004(b).2 of §20.1004) that is used to derive dose equivalent from absorbed dose.

Quarter means a period of time equal to one-fourth of the year observed by the licensee (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Rad (See §20.1004).

Radiation (ionizing radiation) means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radioor microwaves, or visible, infrared, or ultraviolet light.

Radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Reference man means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to

standardize results of experiments and to relate biological insult to a common base.

Rem (see §20.1004).

Respiratory protective device means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Sanitary sewerage means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

Shallow-dose equivalent (Hs), which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm 2) averaged over an area of 1 square centimeter.

Sievert (See §20.1004).

Site boundary means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

Source material means—

(1) Uranium or thorium or any combination of uranium and thorium in any physical or chemical form; or

(2) Ores that contain, by weight, one-twentieth of 1 percent (0.05 percent), or more, of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

Special nuclear material means—

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing but does not include source material.

Stochastic effects means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Total Effective Dose Equivalent (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Uranium fuel cycle means the operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing of spent uranium fuel to the extent that these activities directly support the production of electrical power for public use. Uranium fuel cycle does not include mining operations, operations at waste disposal sites, transportation of radioactive material in support of these operations, and the reuse of recovered non-uranium special nuclear and byproduct materials from the cycle.

Very high radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or from any surface that the radiation penetrates.

(NOTE: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts)).

Week means 7 consecutive days starting on Sunday.

Weighting factor wT , for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of

that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ or tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bonsurfaces	0.03
Remainder	[1] 0.30
Whole Body	[2] 1.00

[1] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

[2] For the purpose of weighting the external whole body dose (for adding it to the intemal dose), a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

Whole body means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

Working level (WL) is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy.

Working level month (WLM) means an exposure to 1 working level for 170 hours (2,000 working hours per year/12 months per year = approximately 170 hours per month).

Year means the period of time beginning in January used to determine compliance with the provisions of this part. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

[56 FR 23391, May 21, 1991, as amended at 57 FR 57878, Dec. 8, 1992; 58 FR 7736, Feb. 9, 1993]

§20.1004 Units of radiation dose

(a) Definitions. As used in this part, the units of radiation dose are:

Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram (100 rads).

Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

Rem is the special unit of any of the quantities expressed as dose equivalent.

The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert).

Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

(b) As used in this part, the quality factors for converting absorbed dose to dose equivalent are shown in table 1004(b).1.

(c) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in paragraph (b) of this section, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the regulations in this part, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from table 1004(b).2 to convert a measured tissue dose in rads to dose equivalent in rems.

TABLE 1004(b).1—QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Type of radiation	Quality factor (Q)	Absorbed dose equal to a unitdose equivalent [a]
X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragmentsand heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a] Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

TABLE 1004(b).2—MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron energy (MeV)	Quality factor[a] (Q)	Fluence per unit dose equivalent[b] (neutrons cm^{-2} rem^{-1})
(thermai)..	2.5×10^{-8}	2	980×10^{6}
	1×10^{-7}	2	980×10^{6}
	1×10^{-6}	2	810×10^{6}
	1×10^{-5}	2	810×10^{6}
	1×10^{-4}	2	840×10^{6}
	1×10^{-3}	2	980×10^{6}
	1×10^{-2}	2.5	1010×10^{6}
	1×10^{-1}	7.5	170×10^{6}
	5×10^{-1}	11	39×10^{6}
	1	11	27×10^{6}
	2.5	9	29×10^{6}
	5	8	23×10^{6}
	7	7	24×10^{6}
	10	6.5	24×10^{6}
	14	7.5	17×10^{6}
	20	8	16×10^{6}
	40	7	14×10^{6}
	60	5.5	16×10^{6}
	1×10^{2}	4	20×10^{6}
	2×10^{2}	3.5	19×10^{6}
	3×10^{2}	3.5	16×10^{6}
	4×10^{2}	3.5	14×10^{6}

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.

[b] Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

§20.1005 Units of radioactivity

For the purposes of this part, activity is expressed in the special unit of curies (Ci) or in the SI unit of becquerels (Bq), or their multiples, or disintegrations (transformations) per unit of time.

(a) One becquerel=1 disintegration per second (s^{-1}).

(b) One curie = 3.7×10^{10} disintegrations per second = 3.7×10^{10} becquerels=2.22×10^{12} disintegrations per minute.

[56 FR 23391, May 21, 1991; 56 FR 61352, Dec. 3, 1991]

§20.1006 Interpretations

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by an officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§20.1007 Communications

Unless otherwise specified, communications or reports concerning the regulations in this part should be addressed to the Executive Director for Operations. U.S. Nuclear Regulatory Commission, Washington. DC 20555. A communication, report, or application may be delivered in person to the Office of the Executive Director for Operations, 11555 Rockville Pike. Rockville, MD 20852.

§20.1008—[Reserved]

§20.1009 Reporting, recording, and application requirements: OMB approval

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq*.). OMB has approved the information collection requirements contained in this part under control number 3150–0014.

(b) The approved information collection requirements contained in this part appear in §§20.1101, 20.1202, 20.1204, 20.1206, 20.1301, 20.1501, 20.1601, 20.1703, 20.1901, 20.1902, 20.1904, 20.1906, 20.2002, 20.2004, 20.2006, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108, 20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2206, and appendix F to 20.1001–20.2401.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §20.2104, NRC Form 4 is approved under control number 3150–0005.

(2) In §§20.2106 and 20.2206, NRC Form 5 is approved under control number 3150–0006.

[57 FR 57878, Dec. 8, 1992]

Subpart B—Radiation Protection Programs

SOURCE: 56 FR 23396, May 21, 1991, unless otherwise noted.

§20.1101 Radiation protection programs

(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure

compliance with the provisions of this part. (See § 20.2102 for recordkeeping requirements relating to these programs.)

(b) The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(c) The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Subpart C—Occupational Dose Limits

SOURCE: 56 FR 23396, May 21, 1991, unless otherwise noted.

§ 20.1201 Occupational dose limits for adults.

(a) The licensee shall control the occupational dose to individual adults, except for planned special exposures under § 20.1206, to the following dose limits.

(1) An annual limit, which is the more limiting of—

(i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or

(ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(2) The annual limits to the lens of the eye, to the skin, and to the extremities, which are:

(i) An eye dose equivalent of 15 rems (0.15 Sv), and

(ii) A shallow-dose equivalent of 50 rems (0.50 Sv) to the skin or to any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (see § 20.1206(e)(1)) and during the individual's lifetime (see §20.1206(e)(2)).

(c) The assigned deep-dose equivalent and shallow-dose equivalent must be for the part of the body receiving the highest exposure. The deep-dose equivalent, eye dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in table 1 of appendix B to §§ 20.1001–20.2401 and may be used to determine the individual's dose (see § 20.2106) and to demonstrate compliance with the occupational dose limits.

(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see footnote 3 of appendix B to §§ 20.1001–20.2401).

(f) The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (see § 20.2104(e)).

§ 20.1202 Compliance with requirements for summation of external and internal doses.

(a) If the licensee is required to monitor under both §§ 20.1502(a) and (b), the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only under §20.1502(a) or only under § 20.1502(b), then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in paragraph (b) of this section and the conditions in paragraphs (c) and (d) of this section.

(NOTE: The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.)

(b) *Intake by inhalation*. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit.

of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 34 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 34 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 34.1, 34.2, 34.3, 34.8, 34.11, 34.51, 34.61, and 34.63.

[57 FR 55074, Nov. 24, 1992]

APPENDIX A TO PART 34

I. FUNDAMENTALS OF RADIATION SAFETY

A. Characteristics of gamma radiation.
B. Units of radiation dose (mrem) and quantity of radioactivity (curie).
C. Hazards of exposure to radiation.
D. Levels of radiation from licensed material.
E. Methods of controlling radiation dose:
1. Working time.
2. Working distances.
3. Shielding.

II. RADIATION DETECTION INSTRUMENTATION TO BE USED

A. Use of radiation survey instruments:
1. Operation.
2. Calibration.
3. Limitations.
B. Survey techniques.
C. Use of personnel monitoring equipment:
1. Film badges and thermoluminescent dosimeters (TLD's).
2. Pocket dosimeters.
3. Alarm ratemeters

III. RADIOGRAPHIC EQUIPMENT TO BE USED

A. Remote handling equipment.
B. Radiographic exposure devices.
C. Storage containers.

IV. INSPECTION AND MAINTENANCE PERFORMED BY THE RADIOGRAPHERS

V. CASE HISTORIES OF RADIOGRAPHY ACCIDENTS

[44 FR 50808, Aug. 30, 1979, as amended at 55 FR 853, Jan. 10, 1990]

PART 35-MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A—General Information

Subpart B—General Administrative Requirements

Subpart C—General Technical Requirements

Subpart D—Uptake, Dilution, and Excretion

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

SOURCE: 51 FR 36951, Oct. 16, 1986, unless otherwise noted.

Subpart A—General Information

§ 35.1 Purpose and scope.

This part prescribes requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, and 170 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 Definitions.

Address of use means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.

Agreement State means any State with which the Commission or the Atomic Energy

Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

ALARA (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

(1) Consistent with the purpose for which the licensed activity is undertaken.

(2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and

(3) In relation to utilization of nuclear energy in the public interest.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.

Authorized user means a physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

Brachytherapy source means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Dental use means the intentional external administration of the radiation from byproduct material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

Management means the chief executive officer or that person's delegate or delegates.

Medical Institution means an organization in which several medical disciplines are practiced.

Medical use means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Ministerial change means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

Misadministration means the administration of:

(1) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I–125 or I–131:

(i) Involving the wrong patient or wrong radiopharmaceutical, or

(ii) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I–125 or I–131:

(i) Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or

(ii) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(3) A gamma stereotactic radiosurgery radiation dose:

(i) Involving the wrong patient or wrong treatment site; or

(ii) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

(4) A teletherapy radiation dose:

(i) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;

(ii) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(iii) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

(iv) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(5) A brachytherapy radiation dose:

(i) Involving the wrong patient. wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site):

(ii) Involving a sealed source that is leaking;

(iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(iv) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I–125 or I–131, both:

(i) Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) When the dose to the patient exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

Mobile nuclear medicine service means the transportation and medical use of byproduct material.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Podiatric use means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented:

(1) In a written directive; or

(2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose means:

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive; or

(3) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

Radiation Safety Officer means the individual identified as the Radiation Safety Officer on a Commission license.

Recordable event means the administration of:

(1) A radiopharmaceutical or radiation without a written directive where a written directive is required;

(2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(3) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I–125 or I–131 when both:

(i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

(ii) The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;

(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I–125 or I–131: the the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

(5) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or

(6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Teletherapy physicist means the individual identified as the teletherapy physicist on a Commission license.

Visiting authorized user means an authorized user who is not identified as an authorized user on the license of the licensee being visited.

Written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I–125 or 1–131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I–125 or I–131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(5) For high dose rate remote after loading brachytherapy: the radioisotope, treatment site, and total dose; or

(6) For all other brachytherapy:

(i) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

[51 FR 36951, Oct. 16, 1986, as amended at 56 FR 34120, July 25, 1991]

§ 35.5 Maintenance of records

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[53 FR 19247, May 27, 1988]

§ 35.8 Information collection requirements: OMB approval

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29, 35.31, 35.50, 35.51, 35.53, 35.59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

(1) In § 35.12, Form NRC-313 is approved under control number 3150-0120.

(d) OMB has assigned control number 3150-0171 for the information collection

requirements contained in §§ 35.32 and 35.33.

[51 FR 36951, Oct. 16, 1986, as amended at 57 FR 41378, Sept. 10, 1992]

§ 35.11 License required

(a) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) of this section.

(b) An individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.25, unless prohibited by license condition.

§ 35.12 Application for license, amendment, or renewal

(a) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, and 35.500 of this part must be made by filing an original and one copy of Form NRC–313, ''Application for Materials License.'' For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(c) An application for a license for medical use of byproduct material as described in § 35.600 of this part must be made by filing an original and one copy of Form NRC–313. For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(d) For copies of regulatory guides, application forms, or to submit an application or an amendment request, refer to § 30.6 of this chapter.

§ 35.13 License amendments

A licensee shall apply for and must receive a license amendment:

(a) Before it receives or uses byproduct material for a clinical procedure permitted under this Part but not permitted by the license issued pursuant to this part;

(b) Before it permits anyone, except a visiting authorized user described in § 35.27, to work as an authorized user under the license;

(c) Before it changes Radiation Safety Officers or Teletherapy Physicists;

(d) Before it orders byproduct material in excess of the amount, or radionuclide or form different than authorized on the license; and

(e) Before it adds to or changes the areas of use or address or addresses of use identified in the application or on the license.

§ 35.14 Notifications

A licensee shall notify the Commission by letter within thirty days when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change, or when the licensee's mailing address changes. The licensee shall mail the report to the appropriate address identified in § 30.6 of this chapter.

§ 35.18 License issuance

The Commission shall issue a license for the medical use of byproduct material for a term of five years if:

(a) The applicant has filed Form NRC–313 "Application for Materials License" in accordance with the instructions in § 35.12;

(b) The applicant has paid any applicable fee as provided in part 170 of this chapter;

(c) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and

(d) The applicant meets the requirements of part 30 of this chapter.

§ 35.19 Specific exemptions

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations

in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The Commission will review requests forexemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes.

Subpart B—General Administrative Requirements

§ 35.20 ALARA program

(a) Each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

(b) To satisfy the requirement of paragraph (a) of this section:

(1) At a medical institution, management, the Radiation Safety Officer, and all authorized users must participate in the program as requested by the Radiation Safety Committee.

(2) For licensees that are not medical institutions, management and all authorized users must participate in the program as requested by the Radiation Safety Officer.

(c) The program must include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of byproduct material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for all personnel who work with or in the vicinity of byproduct material. The purpose of the review is to ensure that licensees make a reasonable effort to maintain individual and collective occupational doses ALARA.

§ 35.21 Radiation Safety Officer

(a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

(b) The Radiation Safety Officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Establish, collect in one binder or file, and implement written policy and procedures for:

(i) Authorizing the purchase of byproduct material;

(ii) Receiving and opening packages of byproduct material;

(iii) Storing byproduct material;

(iv) Keeping an inventory record of byproduct material;

(v) Using byproduct material safely;

(vi) Taking emergency action if control of byproduct material is lost;

(vii) Performing periodic radiation surveys;

(viii) Performing checks of survey instruments and other safety equipment;

(ix) Disposing of byproduct material;

(x) Training personnel who work in or frequent areas where byproduct material is used or stored;

(xi) Keeping a copy of all records and reports required by the Commission regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

(3) Brief management once each year on the byproduct material program;

(4) Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure;

(5) Establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radia tion Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;

(6) For medical use not at a medical institution, approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management; and

(7) For medical use at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

§ 35.22 Radiation Safety Committee.

Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material.

(a) Each Committee must meet the following administrative requirements:

(1) Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The Committee must meet at least quarterly.

(3) To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

(4) The minutes of each Radiation Safety Committee meeting must include:

(i) The date of the meeting;

(ii) Members present;

(iii) Members absent;

(iv) Summary of deliberations and discussions;

(v) Recommended actions and the numerical results of all ballots; and

(vi) ALARA program reviews described in § 35.20(c).

(5) The Committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

(b) To oversee the use of licensed material, the Committee must:

(1) Review recommendations on ways to maintain individual and collective doses ALARA;

(2) Review, on the basis of safety and with regard to the training and experience standards in subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal;

(3) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under § 35.31 of this part;

(4) Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with byproduct material;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken; and

(6) Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

§ 35.23 Statements of authority and responsibilities.

(a) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority, organizational freedom, and management prerogative, to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions; and

(3) Verify implementation of corrective actions.

(b) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, and retain the current edition of these statements as a record until the Commission terminates the license.

§ 35.25 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by § 35.11(b) of this part shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material and

in the licensee's written quality management program;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

(3) Periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

(b) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

[51 FR 36951, Oct. 16, 1991, as amended at 56 FR 34121, July 25, 1991]

§ 35.27 Visiting authorized user.

(a) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:

(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of a license issued by the Commission or an Agreement State, or a permit issued by a Commission or Agreement State broad licensee that is authorized to permit medical use, that identifies the visiting authorized user by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by the license or permit are performed by that individual.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in paragraph (a) of this section.

(c) A licensee shall retain the records specified in this section for three years after the visiting authorized user's last use of licensed material, but may discard the records if the visiting authorized user has been listed as an authorized user on the licensee's license.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.

(a) The Commission will license mobile nuclear medicine service only in accordance with subparts D. E and H of this part and § 31.11 of this chapter.

(b) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of byproduct material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for three years after the last provision of service.

(c) If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in this chapter while the mobile nuclear medicine service is under the client's direction.

(d) A mobile nuclear medicine service may not order byproduct material to be delivered directly from the manufacturer or distributor to the client's address of use.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.31 Radiation safety program changes.

(a) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in §§ 35.13 and 35.606 of this part. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the regulations and the license.

(b) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

§ 35.32 Quality management program.

(a) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive 1 is prepared for:

(i) Any teletherapy radiation dose;

(ii) Any gamma stereotactic radiosurgery radiation dose;

(iii) Any brachytherapy radiation dose;

(iv) Any administration of quantities greater than 30 microcuries of either sodium iodide I–125 or I–131; or

(v) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I–125 or I–131;

(2) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(b) The licensee shall:

(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

A representative sample of patient administrations,

(ii) All recordable events, and

(iii) All misadministrations to verify compliance with all aspects of the

quality management program; these reviews shall be conducted at

intervals no greater than 12 months;

(2) Evaluate each of these reviews to determine the effectiveness of the

quality management program and, if required, make modifications to

meet the objectives of paragraph (a) of this section; and

(3) Retain records of each review, including the evaluations and findings

of the review, in an auditable form for three years.

(c) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(1) Assembling the relevant facts including the cause;

(2) Identifying what, if any, corrective action is required to prevent recurrence; and

(3) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action if any, was taken.

[1] If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

(d) The licensee shall retain:

(1) Each written directive; and

(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph (a)(1) above, in an auditable form, for three years after the date of administration.

(e) The licensee may make modifications to the quality management program to increase the programs' efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the appropriate NRC Regional Office within 30 days after the modification has been made.

(f)(1) Each applicant for a new license, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 a quality management program as part of the application for a license and implement the program upon issuance of the license by the NRC.

(2) Each existing licensee, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 by January 27, 1992 a written certification that the quality management program has been implemented along with a copy of the program.

[56 FR 34121, July 25, 1991]

§ 35.33 Notifications, reports, and records of misadministrations.

(a) For a misadministration:

(1) The licensee shall notify by telephone the NRC Operations Center [2] no later than the next calendar day after discovery of the misadministration.

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

(3) The licensee shall notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the patient was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

[2] The commercial telephone number of the NRC Operations Center is (301) 951-0550.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

[56 FR 34122, July 25, 1991]

§ 35.49 Suppliers.

A licensee may use for medical use only:

(a) Byproduct material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the regulations in part 30 and § 32.72, 32.73, or 32.74 of this chapter or the equivalent regulations of an Agreement State;

(b) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval by the Commission pursuant to § 32.73 or an Agreement State under equivalent regulations for the preparation of radiopharmaceuticals for medical use; and

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to part 30 of this chapter or the equivalent regulations of an Agreement State.

Subpart C—General Technical Requirements

§ 35.50 Possession, use, calibration, and check of dose calibrators.

(a) A medical use licensee authorized to administer radiopharmaceuticals shall have in its possession a dose calibrator and use it to measure the amount of activity administered to each patient.

(b) A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this paragraph, the check must be done on a frequently used setting with a sealed source of not less than 10 microcuries of radium-226 or 50 microcuries of any other photon-emitting radionuclide;

(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator.

(d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(e) A licensee shall retain a record of each check and test required by this section for three years unless directed otherwise. The records required in paragraphs (b)(1) through (b)(4) of this section must include:

(1) For paragraph (b)(1) of this section, the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check;

(2) For paragraph (b)(2) of this section, the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date

of the test, the results of the test, and the signature of the Radiation Safety Officer;

(3) For paragraph (b)(3) of this section, the model and serial number of the dose calibrator, the calculated activities, the measured activities, thedate of the test, and the signature of the Radiation Safety Officer; and

(4) For paragraph (b)(4) of this section, the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

[51 FR 36951. Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.51 Calibration and check of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part before first use, annually, and following repair. The licensee shall:

(1) Calibrate all scales with readings up to 1000 millirem per hour with a radiation source;

(2) Calibrate two separated readings on each scale that must be calibrated; and

(3) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(b) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(c) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.

(d) A licensee shall retain a record of each survey instrument calibration for three years. The record must include:

(1) A description of the calibration procedure; and

(2) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.53 Measurement of radiopharmaceutical dosages.

A licensee shall:

(a) Measure the activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a photon-emitting radionuclide before medical use;

(b) Measure the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries or less of a photon-emittingradionuclide before medical use to verify that the dosage does not exceed 10 microcuries;

(c) Retain a record of the measurements required by this section for three years. To satisfy this requirement, the record must contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's name, and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries;

(4) Date and time of the measurement; and

(5) Initials of the individual who made the record.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.57 Authorization for calibration and reference sources.

Any person authorized by § 35.11 of this part for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by a person licensed pursuant to § 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 15 millicuries each;

(b) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life not longer than 100 days in individual amounts not to exceed 15 millicuries;

(c) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life longer than 100 days in individual amounts not to exceed 200 microcuries each; and

(d) Technetium-99m in individual amounts not to exceed 50 millicuries.

§ 35.59 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall:

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State and described in the label or brochure that accompanies the source.

(c) To satisfy the leak test requirements of this section, the licensee must:

(1) Take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample;

(2) Take teletherapy and other device source test samples when the source is in the "off" position; and

(3) Measure the sample so that the leakage test can detect the presence of 0.005 microcuries of radioactive material on the sample.

(d) A licensee shall retain leakage test records for five years. The records must contain the model number, and serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.

(e) If the leakage test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements in parts 20 and 30 of this chapter; and

(2) File a report within five days of the leakage test with the appropriate NRC Office listed in § 30.6 of this chapter, with a copy to Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, describing the equipment involved, the test results, and the action taken.

(f) A licensee need not perform a leakage test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 100 microcuries or less of beta or gammaemitting
material or 10 microcuries or less of alpha-emitting material;

(4) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within six months before the date of use or transfer; and

(5) Seeds of iridium-192 encased in nylon ribbon.

(g) A licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession. The licensee shall retain each inventory record for five years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

(h) A licensee in possession of a sealed source or brachytherapy source shall measure the ambient dose rates quarterly in all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(i) A licensee shall retain a record of each survey required in paragraph (h) of this section for three years. The record must include the date of thesurvey, a plan of each area that

was surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the survey instrument used, and the signature of the Radiation Safety Officer.

[51 FR 36951, Oct. 16, 1986, as amended at 52 FR 31611, Aug. 21, 1987; 53 FR 19247, May 27, 1988]

§ 35.60 Syringe shields and labels.

(a) A licensee shall keep syringes that contain byproduct material to be administered in a radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

(c) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient.

§ 35.61 Vial shields and labels.

(a) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

(a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

(c) A licensee shall conduct the surveys required by paragraphs (a) and (b) of this section so as to be able to detect dose rates as low as 0.1 millirem per hour.

(d) A licensee shall establish radiation dose rate trigger levels for the surveys required by paragraphs (a) and (b) of this section. A licenseeshall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(f) A licensee shall conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

(g) A licensee shall establish removable contamination trigger levels for the surveys required by paragraph (e) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the trigger level.

(h) A licensee shall retain a record of each survey for three years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

(a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

(1) The measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter; or

(2) The activity in the patient is less than 30 millicuries.

(b) A licensee may not authorize release from confinement for medical care of any patient administered a permanent implant until the measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter.

§ 35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.

A licensee providing mobile nuclear medicine service shall:

(a) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(b) Bring into each address of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste;

(c) Secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use;

(d) Check survey instruments and dose calibrators as described in § 35.50 and 35.51, and check all other transported equipment for proper function before medical use at each address of use;

(e) Carry a radiation detection survey meter in each vehicle that is being used to transport byproduct material, and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed;

(f) Retain a record of each survey required in paragraph (e) of this section for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who performed the survey.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.90 Storage of volatiles and gases.

A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee shall store a multi-dose container in a fume hood after drawing the first dosage from it.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of § 20.2001 of this chapter if it:

(1) Holds byproduct material for decay a minimum of ten half-lives; (2) Monitors byproduct material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section for three years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

Subpart D—Uptake, Dilution, and Excretion

§ 35.100 Use of radiopharmaceuticals for uptake, dilution and excretion studies.

A licensee may use any byproduct material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and

Drug Administration (FDA) has accepted a ''Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

§ 35.120 Possession of survey instrument.

A licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.

Subpart E—Imaging and Localization

§ 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

(a) A licensee may use any byproduct material in a diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing byproduct material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

(b) A licensee shall elute generators and prepare reagent kits in accordance with the manufacturer's instructions.

(c)(1) From August 23, 1990, to December 31, 1994, a licensee may depart from the manufacturer's instructions for eluting generators and preparing reagent kits for which the Food and Drug Administration (FDA) has approved a "New Drug Application" (NDA), by following the directions of an authorized user physician.

(2) Nothing in this section relieves the licensee from complying with other applicable NRC, FDA, and other Federal or State regulations.

[51 FR 36951, Oct. 16, 1986, as amended at 57 CFR 45568, Oct. 2, 1992; 58 FR 39132, July 22, 1993]

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each elate or extract.

(c) A licensee that must measure molybdenum concentration shall retain a record of each measurement for three years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries, the measured activity of the molybdenum expressed in microcuries, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the initials of the individual who made the measurement.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.205 Control of aerosols and gases.

(a) A licensee that administers radioactive aerosols or gases shall do so in a room with a system that will keep airborne concentrations within the limits prescribed by § 20.1301 of this chapter. The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(b) A licensee shall administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms.

(c) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit listed in § 20.1301 of this chapter. The calculation must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

(d) A licensee shall make a record of the calculations required in paragraph (c) of this section that includes the assumptions, measurements, and calculations made and shall retain

the record for the duration of use of the area. A licensee shall also post the calculated time and safety measures to be instituted in case of a spill at the area of use.

(e) A licensee shall check the operation of reusable collection systems each month, and measure the ventilation rates available in areas of radioactive gas use each six months.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 27667. July 22, 1988; 58 FR 67660, Dec. 22, 1993]

§35.220 Possession of survey instruments.

A licensee authorized to use byproduct material for imaging and localization studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart F—Radiopharmaceuticals for Therapy

§35.300 Use of radiopharmaceuticals for therapy.

(a) A licensee may use any byproduct material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.

(b) (1) From August 23, 1990, to December 31, 1994, a licensee may depart from the package insert instructions regarding indications or methods of administration for a radiopharmaceutical for which the Food and Drug Administration (FDA) has approved a "New Drug Application" (NDA), provided that the authorized user physician has prepared a written directive as required by §35.32(a).

(2) Nothing in this section relieves the licensee from complying with other applicable NRC, FDA, and other Federal or State regulations.

[51 FR 36951. Oct. 16, 1986. as amended at 55 FR 34518. Aug. 23, 1990; 57 FR 45568, Oct. 2, 1992; 58 FR 39132, July 22, 1993]

§35.310 Safety instruction.

(a) A licensee shall provide radiation safety instruction for all personnel caring for the patient receiving radiopharmaceutical therapy and hospitalized for compliance with §35.75 of this chapter. To satisfy this requirement, the instruction must describe the licensee's procedures for:

(1) Patient control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer in case of the patient's death or medical emergency.

(b) A licensee shall keep for three years a list of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§35.315 Safety precautions.

(a) For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with §35.75 of this chapter, a licensee shall:

(1) Provide a private room with a private sanitary facility;

(2) Post the patient's door with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;

(3) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of part 20 of this chapter, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in

millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(5) Either monitor material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.

(6) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient.

(7) Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and

(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by §20.1206(a) of this chapter a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§35.320 Possession of survey instruments.

A licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart G—Sources for Brachytherapy

§35.400 Use of sources for brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(d) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(e) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

(f) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer.

(g) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

[51 FR 36951, Oct. 16, 1986, as amended at 54 FR 41821, Oct. 12, 1989]

§35.404 Release of patients treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of patient surveys for three years. Each record must include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirem per hour and measured at one meter from the patient, he survey instrument used, and the initials of the individual who made the survey.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§35.406 Brachytherapy sources inventory.

(a) Promptly after removing them from a patient, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

(b) A licensee shall make a record of brachytherapy source use which must include:

(1) The names of the individuals permitted to handle the sources.

(2) The number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage;

(3) The number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(c) Immediately after implanting sources in a patient the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(d) A licensee shall retain the records required in paragraphs (b) and (c) of this section for three years.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§35.410 Safety instruction.

(a) The licensee shall provide radiation safety instruction to all personnel caring for the patient undergoing implant therapy. To satisfy this requirement, the instruction must describe:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions in case of a dislodged source;

(3) Procedures for patient control;

(4) Procedures for visitor control; and

(5) Procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

(b) A licensee shall retain for three years a record of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§35.415 Safety precautions.

(a) For each patient receiving implant therapy, a licensee shall:

(1) Not quarter the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of §20.1301(a) of this chapter at a distance of one meter from the implant;

(2) Post the patient's door with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;

(3) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer; and

(4) Promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Part 20 of this chapter, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(5) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§35.420 Possession of survey instrument.

A licensee authorized to use byproduct material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart H—Sealed Sources for Diagnosis

§35.500 Use of sealed sources for diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Iodine-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis; and

(b) Iodine-125 as a sealed source in a portable imaging device.

§35.520 Availability of survey instrument.

A licensee authorized to use byproduct material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour. The instrument must have been calibrated in accordance with §35.51 of this part.

Subpart I—Teletherapy

§35.600 Use of a sealed source in a teletherapy unit.

The regulations and provisions of this subpart govern the use of teletherapy units for medical use that contain a sealed source of cobalt-60 or cesium-137.

§35.605 Maintenance and repair restrictions.

Only a person specifically licensed by the Commission or an Agreement State to perform teletherapy unit maintenance and repair shall:

(a) Install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or

(b) Maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

§35.606 License amendments.

In addition to the changes specified in §35.13 of this part, a licensee shall apply for and must receive a license amendment before:

(a) Making any change in the treatment room shielding;

(b) Making any change in the location of the teletherapy unit within the treatment room;

(c) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(d) Relocating the teletherapy unit; or

(e) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

§35.610 Safety instruction.

(a) A licensee shall post instructions at the teletherapy unit console. To satisfy this requirement, these instructions must inform the operator of:

(1) The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;

(2) The procedure to be followed if:

(i) The operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and

(ii) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(b) A licensee shall provide instruction in the topics identified inparagraph (a) of this section to all individuals who operate ateletherapy unit.

(c) A licensee shall retain for three years a record of individuals receiving instruction required by paragraph (b) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.615 Safety precautions.

(a) A licensee shall control access to the teletherapy room by a door at each entrance.

(b) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that will:

(1) Prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;

(2) Turn the primary beam of radiation off immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(c) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(d) A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(1) A radiation monitor must provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source, and must be observable by an individual entering the teletherapy room.

(2) A radiation monitor must be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

(3) A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

(4) A licensee shall maintain a record of the check required by paragraph (d)(3) of this section for three years. The record must include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

(5) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in paragraph (d)(4) of this section.

(6) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(e) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.620 Possession of survey instrument.

A licensee authorized to use byproduct material in a teletherapy unit shall have in its possession either a portable radiation detection survey instrument capable of detecting dose rate over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1,000 millirem per hour.

§ 35.630 Dosimetry equipment.

(a) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previ-

ous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(b) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section, the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

[51 FR 36951, Oct. 16, 1986, as amended at 56 FR 23471, May 21, 1991]

§ 35.632 Full calibration measurements.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of:

(1) The output within ±3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer constancy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in *Physics in Medicine and Biology* Vol. 16, No. 3, 1971, pp. 379–396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in *Medical Physics* Vol. 10, No. 6, 1983, pp. 741–771, and Vol. 11, No. 2, 1984, p. 213. (Both of these references have been approved for incorporation by reference by the Director of the Federal Register. Copies of the documents are available for inspection at the NRC Library, 7920 Norfolk Avenue, Bethesda, Maryland 20814. Copies of the documents are also on file at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC. A notice of any change in the material will be published in the FEDERAL REGISTER.)

(e) A licensee shall correct mathematically the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding one month for cobalt-60 or six months for cesium-137.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the licensee's teletherapy physicist.

(g) A licensee shall retain a record of each calibration for the duration of use of the teletherapy unit source. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer linearity and constancy, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 43420, Oct. 27, 1988; 57 FR 61786, Dec. 29, 1992]

§ 35.634 Periodic spot-checks.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(1) Timer constancy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b) of this part; and

(6) The difference between the measurement made in paragraph (b)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with procedures established by the teletherapy physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the teletherapy physicist review the results of each spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for three years.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month that assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) A licensee shall arrange for prompt repair of any system identified in paragraph (d) of this section that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section for three years. The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.636 Safety checks for teletherapy facilities.

(a) A licensee shall promptly check all systems listed in § 35.634(d) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by § 35.606 (a) through (d).

(b) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system specified in § 35.634(d), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(c) A licensee shall retain for three years a record of the facility checks following installation of a source. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.641 Radiation surveys for teletherapy facilities.

(a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by § 35.606 (a) through (d), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with § 35.51 of this part to verify that:

(1) The maximum and average dose rates at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 10 millirem per hour and 2 millirem per hour respectively; and

(2) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

(i) Radiation dose quantities per unit time in restricted areas are not likely to cause personnel exposures in excess of the limits specified in § 20.1201 of this chapter; and

(ii) Radiation dose quantities per unit time in unrestricted areas do not exceed the limits specified in § 20.1301 of this chapter.

(b) If the results of the surveys required in paragraph (a) of this section indicate any radiation dose quantity per unit time in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the off position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or

(2) Until the licensee has received a specific exemption pursuant to § 20.1301 of this chapter.

(c) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

[51 FR 36951, Oct. 16, 1986, as amended at 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§ 35.643 Modification of teletherapy unit or room before beginning a treatment program.

(a) If the survey required by § 35.641 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by § 20.1301, before beginning the treatment program the licensee shall:

(1) Either equip the unit with stops or add additional radiation shielding to ensure compliance with § 20.1301(c) of this chapter;

(2) Perform the survey required by § 35.641 again; and

(3) Include in the report required by § 35.645 the results of the initial survey,a description of the modification made to comply with paragraph (a)(1) of this section, and the results of the second survey.

(b) As an alternative to the requirements set out in paragraph (a) of this section, a licensee may request a license amendment under § 20.1301(c) of this chapter that authorizes radiation levels in unrestricted areas greater than those permitted by § 20.1301(a) of this chapter. A licensee may not begin the treatment program until the license amendment has been issued.

[51 FR 36951, Oct. 16, 1986, as amended at 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§ 35.645 Reports of teletherapy surveys, checks, tests, and measurements.

A licensee shall mail a copy of the records required in §§ 35.636, 35.641, 35.643, and the output from the teletherapy source expressed as roentgens or rads per hour at one meter from the source and determined during the full calibration required in § 35.632, to the appropriate Commission Regional Office listed in § 30.6 of this chapter within thirty days following completion of the action that initiated the record requirement.

§ 35.647 Five-year inspection.

(a) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

Subpart J—Training and Experience Requirements

§ 35.900 Radiation Safety Officer.

Except as provided in § 35.901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.32 to be an individual who:

(a) Is certified by:

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology;

(3) American Board of Nuclear Medicine;

(4) American Board of Science in Nuclear Medicine; or

(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy; or

(b) Has had classroom and laboratory training and experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(c) Be an authorized user identified on the licensee's license.

§ 35.901 Training for experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a Commission or Agreement State license before October 1, 1986 need not comply with the training requirements of § 35.900.

§ 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in §§ 35.970 and 35.971, the licensee shall require the authorized user of a radiopharmaceutical in § 35.100(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology; or

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or (b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:

(1) 40 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:

(i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.970 or 35.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology; or

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiopharmaceutical chemistry; and

(v) Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(iii) Calculating and safely preparing patient dosages;

(iv) Using administrative controls to prevent the misadministration of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the elate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes:

(i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§35.930 Training for therapeutic use of radiopharmaceuticals.

Except as provided in §35.970, the licensee shall require the authorized user of radiopharmaceuticals in §35.300 to be a physician who:

(a) Is certified by:

(1) The American Board of Nuclear Medicine; or

(2) The American Board of Radiology in radiology or therapeutic radiology; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

(ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

§35.932 Training for treatment of hyperthyroidism.

Except as provided in §35.970, the licensee shall require the authorized user of only

iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection,

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

§35.934 Training for treatment of thyroid carcinoma.

Except as provided in §35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

§35.940 Training for use of brachytherapy sources.

Except as provided in §35.970, the licensee shall require the authorized user of a brachytherapy source listed in §35.400 for therapy to be a physician who:

(a) Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British ''Fellow of the Faculty of Radiology'' or ''Fellow of the Royal College of Radiology''; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Checking survey meters for proper operation;

(iii) Preparing, implanting, and removing sealed sources;

(iv) Maintaining running inventories of material on hand;

(v) Using administrative controls to prevent the misadministration of byproduct material; and

(vi) Using emergency procedures to control byproduct material; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(i) Examining individuals and reviewing their case histories todetermine their suitability for brachytherapy treatment, and any limitations or contraindications;

(ii) Selecting the proper brachytherapy sources and dose and method of administration;

(iii) Calculating the dose; and

(iv) Post-administration followup and review of case histories in collaboration with the authorized user.

§35.941 Training for ophthalmic use of strontium-90.

Except as provided in §35.970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

(a) 24 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology;

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

(4) Followup and review of each individual's case history.

§35.950 Training for use of sealed sources for diagnosis.

Except as provided in §35.970, the licensee shall require the authorized user of a sealed source in a device listed in §35.500 to be a physician, dentist, or podiatrist who:

(a) Is certified in:

(1) Radiology, diagnostic radiology, or therapeutic radiology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine; or (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) Radiation biology;

(3) Radiation protection; and

(4) Training in the use of the device for the uses requested.

§35.960 Training for teletherapy.

Except as provided in §35.970, the licensee shall require the authorized user of a sealed source listed in §35.600 in a teletherapy unit to be a physician who:

(a) Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology:

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) Review of the full calibration measurements and periodic spot checks;

(ii) Preparing treatment plans and calculating treatment times;

(iii) Using administrative controls to prevent misadministrations;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(v) Checking and using survey meters; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

(ii) Selecting the proper dose and how it is to be administered;

(iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

(iv) Post-administration followup and review of case histories.

§35.961 Training for teletherapy physicist.

The licensee shall require the teletherapy physicist to be an individual who:

(a) Is certified by the American Board of Radiology in:

(1) Therapeutic radiological physics;

(2) Roentgen ray and gamma ray physics;

(3) X-ray and radium physics; or

(4) Radiological physics; or

(b) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in §§35.59, 35.632, 35.634, and 35.641 of this part.

§35.970 Training for experienced authorized users.

Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or pediatric use of byproduct material on a Commission or Agreement State license issued before April 1, 1987 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of subpart J.

§35.971 Physician training in a three month program.

A physician who, before July 1, 1984, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of §§35.910 or 35.920.

§35.972 Recentness of training.

The training and experience specified in this subpart must have been obtained within the five years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subpart K—Enforcement

§35.990 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55074, Nov. 24, 1992]

§35.991 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 35 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§35.1, 35.2, 35.8, 35.12, 35.18, 35.19, 35.57, 35.100, 35.600, 35.901, 35.970, 35.971, 35.990, 35.991, and 35.999.

[57 FR 55074, Nov. 24, 1992]

§35.999 Resolution of conflicting requirements during transition period.

If the rules in this part conflict with the licensee's radiation safety program as identified in its license, and if that license was approved by the Commission before April 1, 1987 and has not been renewed since April 1, 1987, then the requirements in the license will apply. However, if that licensee exercises its privilege to make minor changes in its radiation safety procedures that are not potentially important to safety under §35.31 of this chapter, the portion changed must comply with the requirements of this part. At the time of license renewal and thereafter, these amendments to this part shall apply.

PART 36-LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

Subpart A—General Provisions

Subpart B—Specific Licensing Requirements

Subpart C—Design and Performance Requirements for Irradiators

Subpart D—Operation of Irradiators

Subpart E—Records

Subpart F—Enforcement

E

Nuclear Regulatory Commission Agreement and Non-agreement States

NON-AGREEMENT STATES

Alabama
Arizona
Arkansas
California
Colorado
Florida
Georgia
Illinois
Iowa Rhode
Kansas South
Kentucky
Louisiana
Maine Utah
Maryland
Mississippi
Nebraska
Nevada
New Hampshire
New Mexico
New York
North Carolina
North Dakota
Oregon
Island
Carolina
Tennessee
Texas
Washington

NONAGREEMENT STATES

Alaska
Connecticut
Delaware
District of Columbia
Hawaii
Indiana
Massachusetts
Michigan
Minnesota

Missouri	Idaho
Montana	South Dakota
New Jersey	Vermont
Ohio West	Virginia
Oklahoma	Virginia
Pennsylvania	Wisconsin
	Wyoming

F

Regulatory Chronology

1929	Advisory Committee on X-ray and Radium Protection is established (later becomes National Council on Radiation Protection (NRCP)).
1946	Atomic Energy Act (AEA) (Public Law 79-585, 60 Stat. 755) establishes Atomic Energy Commission (AEC) and Joint Committee on Atomic Energy.
Manhattan Project reactor-produced isotopes are first distributed for medical applications.	
1953	NCRP publishes recommendations on maximum permissible amounts of radioisotopes in the human body and maximum permissible concentrations in air and water.
1954	AEA of 1954 opens nuclear technologies to commercial enterprise.
1956	National Academy of Sciences issues *The Biological Effects of Atomic Radiation*.
1959	Congress establishes Agreement State Program.
	President Eisenhower issues executive order establishing the Federal Radiation Council (FRC).

1960	FRC issues radiation protection guidelines.
1962	Kentucky becomes first Agreement State.
1967	AEC codifies medical regulation into new 10 CFR Part 35. U.S. Public Health Service establishes the National Center for Radiological Health (predecessor to Food and Drug Administration's Bureau of Radiological Health (BRH), which is today part of Center for Devices and Radiological Health (CDRH)).
1968	Radiation Control for Health Safety (RCHS) Act directs Secretary of Health, Education and Welfare to establish and conduct radiation control program.
1972	General Accounting Office (GAO) report advises AEC to strengthen control over medical use of radioactive materials.
1974	Energy Reorganization Act establishes the Nuclear Regulatory Commission (NRC) and the Energy Research and Development Administration (ERDA) to replace the AEC.
1976	Riverside Hospital incident results in overexposure of 393 people. Medical Device Amendments are enacted.
1978	Section 274j of the AEA requires NRC to review Agreement States periodically to ensure compliance with Section 274.
1979	GAO issues report stating that the NRC's reporting requirement does not constitute unprecedented intrusion into medical practice. NRC issues final rule governing proper calibration checks. NRC issues Medical Use Policy, incorporating policy statement with three basic provisions: (1) NRC continues regulating medical uses to protect workers and public; (2) NRC regulates safety of patients where justified by risk and where compliance with voluntary standards is inadequate; (3) NRC minimizes intrusion into medical judgment and other areas of practice of medicine.
1980	Congress grants NRC authority to suspend either all or part of an Agreement State's program.

	Commission approves final rule regarding misadministrations.
	President Carter issues Executive Order 12914, establishing Radiation Policy Council. President Reagan disbands Council the following year.
1981	Consumer-Patient Radiation Health Safety Act is enacted.
1982	BRH and Bureau of Medical Devices (BMD) merge to form new CDRH within the FDA.
1984	Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) is created to coordinate radiation policy among agencies and resolve policy conflicts.
1985	NRC's Office for Analysis and Evaluation of Operational Data issues report finding that quality assurance programs in radiotherapy facilities are inadequate.
1986	Commission instructs staff to formulate rules to strengthen oversight of performance by licensees.
1987	Major revision to Part 35 codifies radiation safety practices that had become standard in licensed medical use.
	EPA implements Federal Radiation Protection Guidance for Occupational Exposure.
1989	NRC proposes performance-based quality assurance rule.
1991	NRC "quality management rule" is finalized, effective January 27, 1992 (effective in Agreement States in January 1995).

G

History of Radiation Regulation in Medicine

This appendix briefly covers the history of the regulation of ionizing radiation in medicine. It begins with a discussion of early guidelines by the scientists involved in the evolving profession. It moves next to descriptions of various forms of governmental regulation, looking at both federal regulation by several agencies and at state regulation. This history is meant to give context to the discussions on regulation contained within the main text of the report.

PROFESSIONAL SELF-REGULATION

Today, regulations to ensure personal safety and public health are considered primarily a governmental responsibility. For several decades after the discovery of ionizing radiation, however, individuals sought protection from the adverse effects of radiation primarily through professional guidelines. Citing the deaths of radiologists, the German Roentgen Society first provided guidelines in 1913 to reduce the dangers of radiation exposure to medical workers (Taylor, 1981). In 1915 and 1921, recommendations in Great Britain to protect x-ray operators included maximum work schedules, required amounts of leisure time, and special accommodations for the workers (British X-Ray and Radium Protection Committee, 1921). In the United States, the American Roentgen Ray Society and the American Radium Society were encouraged by George Pfahler to create specific guidelines for radiation protection. Dr. Pfahler suggested that:

1. The principles of radiology be thoroughly mastered, so that they can be adapted to the individual establishment, for the protection of both operator and patient;

2. A committee of the society be appointed to cooperate with other bodies of national organizations, to study and formulate definite directions and rules of protection;
3. The committee cooperate insofar as possible with the Bureau of Standards in Washington in order to secure definite and permanent products, and possibly definite calibration of units;
4. Radium be insured against loss, so that men will not be suddenly hampered financially and prevented from carrying on the good work which has been started;
5. Every radiologist be provided with legal protection, with protection from insurance companies and the protection and cooperation of his county medical society; [and]
6. Every radiologist in the country associate himself with the American Radium Society, both for his good and the good of the Society. (Taylor, 1979, 2-009-2-010)

The third of Pfahler's recommendations delineates a governmental role in the regulation and control of radiation sources. In 1927, the National Bureau of Standards began a voluntary program to inspect and calibrate radiation equipment and to send government representatives into laboratories to evaluate the safety of radiation sources, including x-ray machines. This program followed the model of a national inspection program initiated in 1921 by the National Physical Laboratory in Great Britain.

The International Commission on Radiological Protection (ICRP) held its formative meeting in 1928 and requested that each represented country develop a coordinated program of radiation control. The U.S. representative, Lauriston Taylor from the U.S. Bureau of Standards, formed the U.S. Advisory Committee on X-Ray and Radium Protection, later named the National Committee (now Council) on Radiation Protection and Measurements (NCRP). The NCRP received a congressional charter in 1964, and to this day it maintains a nongovernmental commitment to the development of guidelines to protect individuals and the public from excessive exposure to radiation.

By 1931, early philosophical constructs of radiation protection had been developed by the ICRP and NCRP, and the concept of "tolerance dose" was adopted as an upper limit for exposure of workers (Hendee, 1995). About the same time, the International Commission on Radiation Units and Measurements (ICRU) defined the unit "roentgen (R)" as the amount of radiation that would produce a certain amount of ionization in a given volume of air at standard temperature and pressure. In 1934 the ICRP established a tolerance dose of 0.2 R per day for exposure of workers to radiation, and in 1936 the NCRP reduced this limit to 0.1 R per day. This limit was maintained through World War II and was applied to workers in the Manhattan Project (Hendee, 1993).

The ICRP and, in the United States, the NCRP have remained to this day as the principal voluntary advisory agencies concerning radiation protection and limits for radiation exposure. In 1954 the NCRP adopted the concept of "maximum permissible dose" in place of "tolerance dose," accepted the use of absorbed dose rather than exposure as a preferred way to express protection limits, and acknowledged the linear, no-threshold model of radiation injury as the guiding philosophy for establishing upper limits for radiation exposure (NCRP, 1954). Over the next 25 years, several other changes were introduced, including use of "effective dose equivalent" in place of absorbed dose as a way to accommodate variations in the effectiveness of different types of radiation to inflict biological damage. In 1977 the ICRP proposed the concept of "effective dose" as an approach that considers the overall impact of irradiating different regions of the body. In the same report (ICRP, 1977), the ICRP recommended that protection standards should be based on acceptable health risks rather than on arbitrary dose limits.

GOVERNMENT REGULATION

NUCLEAR REGULATORY COMMISSION

Atomic Energy Act

The Hiroshima and Nagasaki explosions brought the nuclear age abruptly into worldwide consciousness. The end of World War II gave rise to a bitter dispute in the United States between military leaders and civilian officials concerning the best way to control nuclear energy and inhibit development of nuclear weapons by other countries. This dispute culminated in congressional passage of the Atomic Energy Act (AEA) of 1946. This act affirmed civilian control over nuclear energy while leaving weapons development with the military. The AEA created the Atomic Energy Commission (AEC) to oversee development of nuclear technologies. The AEC's principal function was to foster the continued development of nuclear weapons in the United States, including assurance of a sufficient supply of weapons-grade fissionable material. A secondary purpose of the AEC was to encourage peaceful uses of nuclear energy (Mazuzan and Walker, 1984). By 1954, the Isotopes Division of Oak Ridge National Laboratory had delivered 47,000 shipments of reactor-produced radioactive nuclides around the country, many of which were intended for medical uses.

The AEA also created a congressional Joint Committee on Atomic Energy (JCAE) to provide legislative oversight of the activities of the AEC. In 1952 the JCAE issued a document entitled *Atomic Power and Free Enterprise* that encouraged private enterprise to develop nuclear power for commercial purposes. Two years later President Eisenhower urged Congress to change the AEA to facilitate private development of nuclear technologies for peaceful purposes. In

response, Congress passed the AEA of 1954 that endorsed Eisenhower's Project Plowshare to turn "atomic swords into plowshares." The 1954 AEA qualified the endorsement of peaceful applications of nuclear energy by limiting them "to the maximum extent consistent with the common defense and security and with the health and safety of the public." The act gave the AEC a difficult mandate: it was to encourage a private nuclear enterprise while at the same time regulating its activities to ensure compliance with national security and with personal and public health.

The application of radioactive material in medicine was included within the purview of the AEC's regulatory powers. Concerning biomedical research, the AEC was directed in the 1954 AEA to "exercise its powers in such manner as to insure the continued … research … in … utilization of … radioactive material for medical, biological [and] health … purposes" (AEA, 1954, section 31.a.(3)). This encouragement was balanced by provisions to: "(1) protect health, (2) minimize danger to life or property, and (3) require the reporting and permit the inspection of work performed thereunder, as the Commission may determine" (AEA, 1954, section 31.d). The AEC was authorized

> to issue licenses to persons applying therefore for utilization facilities for use in medical therapy. In issuing such licenses the Commission is directed to permit the widest amount of effective medical therapy possible with the amount of special nuclear material available for such purposes, and to impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect the health and safety of the public. (AEA, 1954, section 104.a)

The dual mandate of the AEC to foster development of nuclear technologies and to protect national security and public health was viewed by many as a set of contradictory objectives. After years of public debate on this issue, Congress passed the Energy Reorganization Act (ERA) in 1974 to separate the two conflicting objectives. A new Energy Research and Development Administration (ERDA, subsequently changed to the cabinet-level Department of Energy (DOE)) assumed "activities relating to research and development on the various sources of energy (and) other functions, including but not limited to the Atomic Energy Commission's military and production activities and its general basic research activities." The act also created the Nuclear Regulatory Commission (NRC) to continue the licensing and related regulatory functions of the Atomic Energy Commission. The NRC was to be directed by five commissioners appointed by the President with approval of the Senate.

Other Federal Agencies

Federal Radiation Council

In 1959, at President Eisenhower's request, the Bureau of the Budget analyzed the radiation protection roles of various federal agencies. Perceiving a conflict of interest within the AEC between its promotion of weapons and energy development and its obligations to protect public health and safety, the Bureau recommended several changes to restore public confidence in federal control of radioactive materials. Among the recommendations was the creation of the Federal Radiation Council (FRC), which comprised the secretaries of the Departments of Commerce, Defense, and Health, Education and Welfare (DHEW), as well as the AEC chairperson.

The FRC was directed to rely on the expertise of the NCRP in proposing recommendations to the President on protection standards. These recommendations were to be limited to general standards and guidance; federal agencies retained their responsibilities for setting legally binding standards within their jurisdictions, and the NCRP retained its unofficial status as an independent voluntary agency. In proposing protection guidelines for workers and the general public, the FRC abandoned the concept of "maximum permissible dose" and substituted the term "radiation protection guide (RPG)." The FRC defined the RPG as "the radiation dose which should not be exceeded without careful consideration of the reasons for doing so; every effort should be made to encourage the maintenance of radiation doses as far below this guide as practicable." The FRC stated that "[t]hese guides are not intended to apply to radiation exposure resulting from natural background or the purposeful exposure of patients by practitioners of the healing arts."

In 1970, President Nixon issued Executive Order No. 3. This order disbanded the FRC, placing its functions within the newly created Environmental Protection Agency (EPA). The plan also transferred to the EPA certain functions of the DHEW Bureau of Radiological Health and of the AEC.

Other Executive Agencies

The Radiation Policy Council (RPC) was established in 1980 by President Carter. One year later, President Reagan disbanded it, creating in its place the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC), which was to coordinate policy and resolve conflicts between agencies. No disputes between agencies were brought before the CIRRPC before its demise in 1995. Neither the RPC nor the CIRRPC had regulatory or enforcement authority, and their power as executive agencies was severely limited.

PHS Radiological Health Program

The U.S. Public Health Service (PHS) has been involved in radiation protection matters since the 1920s. In its early years before World War II, its responsibilities included investigations of radium poisonings of watch dial painters, radium and x-ray hazards in hospitals, and radiation safety programs for photofluorographic technicians. In 1948 the Radiological Health Branch was established to help states limit hazards from the use of radioisotopes and other industrial radiation sources and to assist the AEC in studying effects of nuclear waste in rivers and streams. It also surveyed the use of x-rays in PHS hospitals, provided training in radiation protection for state personnel, and worked with the Department of Defense to monitor fallout from nuclear weapons testing in Nevada and the Pacific.

In 1958 the Surgeon General established the National Advisory Committee on Radiation, which recommended unification of all PHS activities related to radiation control. In response, the PHS established the Division of Radiological Health to conduct research on the effects of radiation, provide technical assistance and training to state radiological health programs, and coordinate with other federal radiation programs. A year later, the Division intensified its radiological health efforts; in particular, it assumed primary responsibility for the collection, analysis, and interpretation of data on environmental radiation levels, assessment of all forms of radiation exposure in the United States, and development of recommendations for acceptable levels of radiation exposure from air, water, milk, medical procedures, and the general environment.

In 1967 the Division was renamed the National Center for Radiological Health. In 1968 the Center was renamed again as the Bureau of Radiological Health (BRH), a component of the PHS's Environmental Control Administration, and was granted regulatory authority to implement the Radiation Control for Health and Safety Act (Public Law 90-602). This act called for a control program over electronic product radiation to include "the development and administration of performance standards to control the emissions of electronic product radiation from electronic products, and the undertaking by public and private organizations of research and investigation into the effects and control of such emissions." As a reflection of its assistance program to states, the BRH supported establishment of the Conference of Radiation Control Program Directors (CRCPD), which continues today as an important organization of state personnel involved in radiation control (see below).

In 1971, pursuant to Executive Order No. 3, the Office of Management and Budget transferred 318 persons and $7 million from the BRH to the newly created EPA. The remaining 389 individuals in the BRH were reassigned to the Food and Drug Administration (FDA) within the PHS. A decade later, the BRH and the Bureau of Medical Devices (BMD) were combined into the Center for Devices and Radiological Health (CDRH) within the FDA.

The CDRH assumed the BMD's responsibility for administering the Medical Device Amendments of the Food, Drug and Cosmetic Act of 1938, as well as continuing BRH obligations for control of radiation from electronic products and medical devices. In 1992 the CDRH was identified as the implementing agency for the Mammography Quality Standards Act (MQSA), to include the publication of national standards for mammography and the establishment of quality control criteria and a certification program for the more than 10,000 medical facilities providing mammography services in the United States. To accommodate the increasing demand for services in the medical device area, voluntary educational programs of the CDRH directed to medical uses of radiation have been curtailed in recent years. Nevertheless, the CDRH has maintained a continued interest in public health aspects of medical uses of radiation.

Environmental Protection Agency

The Environmental Protection Agency was created by Executive Order No. 3 in 1970 to accept certain functions and responsibilities from other federal agencies and departments. These responsibilities included establishment and enforcement of environmental protection standards consistent with national environmental goals. They also involved, as already noted, enforcement of specific radiation criteria and standards that had originally been placed in the AEC and BRH. The FRC was abolished by the executive order.

Since its inception, the EPA has maintained environmental radiation programs such as off-site monitoring around nuclear power plants and radioactive waste disposal sites, and it has been concerned with natural sources of radioactivity such as radon. It did not, however, exercise the authority transferred from the FRC until 1978, when it published a document on medical x-ray guidance for federal agencies. This document contained 12 recommendations that federal agencies were expected to implement. They covered several aspects of medical and dental radiology, including the need for quality assurance programs and procedures to ensure minimal exposures of patients to radiation. Other recommendations were directed at qualifications of prescribers and specifications on radiographic techniques, fetal exposures, proper collimation, and gonadal shielding.

Under its derivative FRC authority, the EPA has published guidance for federal agencies on topics such as occupational radiation exposures and limits on radiation exposure for members of the general population. Although the EPA has not offered recommendations on QA programs for nuclear medicine, it could do so under its FRC-derived authority.

STATE REGULATION

The responsibility for public health and safety has traditionally been assumed principally by the states. With the exception of the use of radioactive byproduct

material, this holds true for all applications of ionizing radiation in medicine. As early as 1949, California consulted the NCRP in an effort to regulate protection of workers exposed to ionizing radiation. In its response, the NCRP seemed more concerned that state regulations not disturb the national uniformity of radiation protection and less concerned that states move toward self-regulation (Taylor, 1981).

When the AEA assigned to the AEC the responsibility for encouraging civilian applications of nuclear energy, together with the exclusive jurisdiction for ensuring health and safety associated with these applications, state governments raised objections. After extended debate, Congress in 1959 revised the 1954 act to establish the Agreement State Program in which AEC responsibilities for health and safety may be delegated to a state. In 1962, Kentucky became the first Agreement State.

Several amendments to the Agreement State Program have been added over the years. In 1978, Congress instructed the NRC to review state programs periodically for compliance, and in 1980 it gave the NRC power to suspend state programs that do not meet minimum standards. In 1995, the NRC applied its quality management rule to all Agreement States.

The CRCPD, established in 1968, is a voluntary network of state and local government officials responsible for radiation regulation and enforcement. The CRCPD periodically updates its *Suggested State Regulations for Control of Radiation*, a publication first issued in 1962 by the Council of State Governments. Most state and local radiation protection programs are based on these suggested guidelines. Despite the fact that the CRCPD is composed of radiation regulators, it has no regulatory authority of its own.

As mentioned above, Congress acted in 1959 to provide a statutory framework for the federal government to relinquish to the states some of its regulatory authority concerning radioactive nuclear and byproduct materials. NRC authority is transferred to a state through a formal agreement between the governor and the NRC. The NRC must conclude that the state's radiation control program "is in accordance with the requirements of [applicable parts of the AEA] and in all other respects compatible with the Commission's program for regulation of such materials, and that the State program is adequate to protect the public health and safety. …" States, for their part, must pass enabling legislation compatible with NRC requirements to establish their authority to enter into these agreements. Once they have done so, and the NRC finds them capable of enforcing the requirements, then state assumption of authority may become effective on the date the agreement is signed.

Although Agreement States regulate their own licensing and enforcement decisions, the NRC maintains significant authority over the states. Biennially, the NRC's Management Review Board reviews each state's performance to ensure that the state's program is adequate and that the state's requirements do not deviate significantly from those of the NRC. The Management Review Board is

made up solely of NRC staff, although Agreement States have requested representation on several occasions. As described in the NRC's "Final Statement of Principles and Policy for the Agreement State Program," the actions of the Management Review Board will include

> (1) periodic assessments of Agreement State radiation control programs against established review criteria; (2) provision of assistance to help address weaknesses or areas within an Agreement State radiation control program requiring improvement; (3) placing a State on probationary status for serious program deficiencies that require heightened oversight; (4) temporary suspensions of an agreement and reassertion of NRC regulatory authority in an emergency if an Agreement State program experiences any immediate program difficulties preventing the State from continuing to ensure adequate protection of the public health and safety. The basis for NRC's actions will be based on a well defined and predictable process, and a performance evaluation which will be consistently and fairly applied.

In 1993, the General Accounting Office (GAO) published a report entitled *Better Criteria and Data Would Help Ensure Safety of Nuclear Materials* that reviewed the comparability of NRC's programs for Agreement States to those of the NRC-regulated states. The report concluded that NRC lacks adequate criteria and data to evaluate the comparative effectiveness of the two programs. It further stated that the NRC does not have common performance indicators on inspection backlogs, radiation overexposures, or frequency of violations; thus, the GAO concluded, the NRC cannot determine if its goals are being met or even if the public is receiving at least a minimum level of protection in different states.

The GAO found that the NRC's criteria for program evaluation are vague; evaluation, therefore, depends on the professional judgment of NRC staff. The GAO concluded that without specific criteria and procedures it is questionable whether the NRC can legitimately initiate the process to revoke its agreement with a state. Hence, it is uncertain whether the Commission adequately protects the public in Agreement States now or could do so in the future.

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H

Public Meeting Documents

ORGANIZATIONS FORMALLY CONTACTED FOR PUBLIC MEETING PARTICIPATION

1.	American Academy of Family Physicians
2.	American Academy of Neurology
3.	American Academy of Ophthalmology
4.	American Academy of Otolaryngology-Head and Neck Surgery
5.	American Academy of Pediatrics
6.	American Association for Thoracic Surgery
7.	American Association of Clinical Urologists
8.	American Association of Dental Examiners
9.	American Association of Operating Room Nurses
10.	American Association of Pathologists
11.	American Association of Physicists in Medicine (AAPM)
12.	American Association of Retired Persons
13.	American Board of Internal Medicine
14.	American Board of Nuclear Medicine (ABNM)
15.	American Board of Radiology (ABR)
16.	American Brachytherapy Society
17.	American Cancer Society
18.	American College of Cardiology
19.	American College of Chest Physicians
20.	American College of Emergency Physicians
21.	American College of Medical Physics

22. American College of Nuclear Medicine
23. American College of Nuclear Physicians (ACNP)
24. American College of Obstetricians and Gynecologists
25. American College of Occupational and Environmental Medicine
26. American College of Physicians
27. American College of Radiation Oncology
28. American College of Radiology (ACR)
29. American College of Surgeons
30. American Federation for Aging Research
31. American Gastroenterological Association
32. American Geriatrics Society
33. American Health Decision
34. American Heart Association
35. American Hospital Association
36. American Institute of Ultrasound in Medicine
37. American Medical Association
38. American Medical Women's Association
39. American Nuclear Society
40. American Nurses Association
41. American Orthopaedic Association
42. American Orthopaedic Foot and Ankle Society
43. American Osteopathic Association
44. American Osteopathic College of Radiology
45. American Pediatric Surgical Association
46. American Pharmaceutical Association Foundation
47. American Public Health Association
48. American Radium Society
49. American Roentgen Ray Society (ARRS)
50. American Society for Pharmacology and Experimental Therapeutics
51. American Society for Radiologic Technologists (ASRT)
52. American Society for Therapeutic Radiology and Oncology
53. American Society of Clinical Oncology
54. American Society of Clinical Pathologists
55. American Society of Internal Medicine
56. American Society of Law, Medicine and Ethics
57. American Society of Neuroradiology
58. American Society of Nuclear Cardiologists
59. American Thoracic Society
60. American Urological Association
61. Appalachian Compact Users of Radioactive Isotopes
62. Association of American Medical Colleges
63. Association of Free Standing Radiation Oncology Centers
64. Association of Pediatric Oncology Nurses
65. Association of University Radiologists

66. Bureau of Radiation Health
67. Cancer Care Inc.
68. Center for Devices and Radiological Health
69. Center for Drug Evaluation and Research
70. Center for Information on Internal Dosimetry of Radiopharmaceuticals
71. Committee on Interagency Research and Policy Coordination (CIRRPC)
72. Center for Medical Consumers
73. College of American Pathologists
74. Conference of Radiation Control Program Directors Inc. (CRCPD)
75. Department of Energy
76. Department of Health and Human Services (DHHS)
77. Elekta Instruments, Inc.
78. Environmental Protection Agency (EPA)
79. Food and Drug Administration (FDA)
80. Group Health Association of America, Inc.
81. Health Care Financing Administration
82. Health Physics Society (HPS)
83. Hospice Education Institute, Inc.
84. Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
85. National Coalition for Cancer Survivorship
86. National Committee on Quality Assurance
87. National Consumers League
88. National Council of Radiation Protection and Measurement
89. National Electrical Manufacturers Association Nuclear Section
90. National Institute for Occupational Safety and Health
91. National Institute of Health Radiation Safety Officers
92. National Institutes of Health/National Cancer Institute
93. New York City Department of Public Health
94. Office of Energy Research
95. Office of Legislation and Policy
96. Office of Nuclear Energy
97. Office of Radiation and Indoor Air
98. Office of Radiation Programs
99. Oncology Nursing Society
100. People's Medical Society
101. Physicians for National Health Program
102. Physicians for Social Responsibility
103. Public Citizen Health Research Group
104. Radiation Research Society
105. Radiological Society of North America (RSNA)
106. Society for Pediatric Radiology
107. Society of Cardiovascular and Interventional Radiology
108. Society of Cardiovascular Anesthesiologists
109. Society of Nuclear Medicine (SNM)

110.	United Cancer Council
111.	Veterans Administration

COMMITTEE FOR REVIEW AND EVALUATION OF THE MEDICAL USE PROGRAM OF THE NUCLEAR REGULATORY COMMISSION

PUBLIC MEETING ANNOUNCEMENT AND REQUEST FOR WRITTEN TESTIMONY

The Institute of Medicine (IOM) Committee for Review and Evaluation of the Medical Use Program of the Nuclear Regulatory Commission (NRC) will hold a public meeting to solicit information from a broad spectrum of organizations and groups regarding the NRC's Medical Use Program and ionizing radiation in medicine.

The following is an open invitation to prepare written testimony for submission to the Committee. A limited number of organizations will be invited to give a brief oral statement at the public meeting, which is scheduled to begin at 9 a.m., October 12, 1994, at the National Academy of Sciences, 2001 Wisconsin Avenue, NW, Green Building Room 130, Washington, DC, 20007. Any organization or individual wishing to be considered for oral presentation must submit a written statement to this office no later than ***September 6, 1994****. Please read further for more details.*

Background

The U.S. Nuclear Regulatory Commission (USNRC) is responsible for regulating the medical (diagnostic and therapeutic) use of byproduct materials, especially for protecting the public from undue risk attendant upon their use in health care applications. (Byproduct materials, or radionuclides, include such substances as cobalt-60, iodine-131, and radium-223 used for diagnosis and treatment of cancer and iodine-125 used for the diagnosis of osteoporosis.) This "medical use" responsibility derives from its more general public health and safety responsibilities for regulating all aspects of nuclear reactor safety.

The Nuclear Regulatory Commission has requested from the Institute of Medicine (IOM) a detailed independent review and evaluation of the adequacy of that program as well as recommendations for needed changes. The IOM has established a 16-member committee of experts to conduct a study that will result in a formal report at the conclusion of this study tentatively scheduled for release December 1995.

Providing Testimony

To respond to this request, the IOM has established a committee of 16 experts representing a wide range of expertise. As part of the committee's activities, written testimony is being solicited from a large number of organizations and groups representing all points of view on the subject. Although a limited number of organizations will be invited to present oral testimony and to respond to the committee's questions, the committee urges you to submit written testimony, which will be given equal consideration to the oral testimony. One invitational session, a day long, will be convened in Washington, D.C. on October 12, 1994. Those organizations and individuals asked to present oral statements will be grouped in panels, asked to confine their remarks to about 5 minutes summarizing their written testimonies, and requested to be prepared to respond to committee members' questions. We can only accommodate a limited number of oral presentations but persons/organizations who wish to be considered for making a brief oral presentation should contact Kate-Louise Gottfried as soon as possible, and no later than **August 23, 1994**. These sessions will be open to the public for observation. **Reporters interested in attending the oral presentation sessions should contact the Office of News and Public Information at 202-334-2138, or through Internet at NEWS@NAS.EDU**.

This hearing provides an opportunity for the committee members to obtain firsthand an extensive range of opinions on the matters under consideration. Written and oral statements will be summarized by staff for the committee after they are completed. The topics to be addressed in the written testimony are provided in the following *Guide to Preparing Testimony*. If a particular question (s) is not relevant to your discipline, or you have no knowledge/experience regarding the area identified, please state this and proceed to the next topic. Finally, the committee is eager to hear from you, not only your criticisms and frustrations about the existing system, but also your realistic recommendations and/or proposals on how to improve the existing system. Please bear this in mind throughout your response to the questions presented.

Guide to Preparing Testimony

First, as background, briefly describe your organization and its activities; existing brochures or publications are acceptable. Then, to the extent possible, please address at least the topics listed below. Your written statement may be as long as you choose. Previously prepared relevant statements may be submitted, but also make sure to respond to the specific questions posed. Please note that all testimony should include a one-to-two page executive summary and a cover letter identifying the name, affiliation, address, and telephone number of the contact person.

TOPICS

The Committee has created four subcommittees that focus on particular aspects of the study. The following questions are listed according to each subcommittee category:

Regulation

1. Does the current regulatory structure pertaining to the medical uses of ionizing radiation provide adequate safeguards to protect the public's health and safety? If not, how might the respective roles of various Federal and State authorities be revised to assure greater patient safety and cost effectiveness?

2a. How does the current regulatory framework—as it applies to ionizing radiation in medicine—affect the practice of medicine?

2b. What is your opinion of the revised quality management rule for misadministrations and the new reporting requirements? How would you change it? What suggestions would you make regarding tracking/ preventing misadministrations? Are the NRC's definitions of misadministrations on target?

3. The Atomic Energy Act of 1954 as amended requires that the Nuclear Regulatory Commission (NRC) regulate reactor-generated byproduct material. Do you believe the act should be amended to require uniform regulation of all ionizing radiation used in medicine under a single Federal agency? If so, which agency? An existing one (i.e., NRC, FDA)? A new one? What role should this agency have vis-à-vis the states?

Data/Risk

4. Do you believe that the current regulatory framework pertaining to the medical uses of ionizing radiation reflects the actual risks associated with the various diagnostic and therapeutic applications?

5. Are your patients informed about the potential risks associated with medical procedures involving ionizing radiation? If yes, how? If not, why not?

6. In your experience, has the evolution of radiation protection standards helped to improve patient safety and welfare? Has it influenced staff safety and welfare?

Quality Management/Quality Assurance

7. Who should bear the ultimate responsibility for devising appropriate quality assurance programs? Professional associations such as JCAHO, ACR, AAPM, etc.? State agencies? Federal agencies?

8. If applicable, what kind of QA program do you have in place? Upon whose expertise did you rely when devising it? How is it working?

Education

9. The 1981 Consumer-Patient Radiation Health Safety Act provides minimum standards by the Federal Government for the accreditation of education programs for persons who administer radiologic procedures and for the certification of such persons. Do you adhere to these standards? Are they effective?
10. What, if any, Federal agency should be responsible for establishing educational standards for accreditation regarding the medical use of ionizing radiation? NRC? FDA? Other? How should the quality of the education programs be judged? What criteria should be applied?
11. How are personnel under authorized users supervised/trained in your facilities? How should they be? How are users trained in applications of new technology? What kind of ongoing training is provided? Should recertification be by test or evidence of continued education?

Other

12. What are your other concerns regarding the regulation of ionizing radiation in medicine?

Please note that all written statements are to be received no later than September 6, 1994. Feel free to distribute this announcement to others who may wish to submit written testimony. Questions regarding the written statements may be directed to Kate-Louise Gottfried, J.D., M.S.P.H., Study Director, at Institute of Medicine, FO 3105, 2101 Constitution Avenue, NW, Washington, DC 20418.

PUBLIC HEARING OCTOBER 12, 1994 ORGANIZATIONS AND INDIVIDUALS SUBMITTING TESTIMONY[1]

Aldrich, Rita
American Association for Nuclear Cardiology (AANC)
American Association of Clinical Endocrinologists
American Association of Physicists in Medicine
American Board of Nuclear Medicine
American Board of Radiology
American Brachytherapy Society
American College of Medical Physics
American College of Nuclear Physicians
American College of Radiology

[1] The organizations in italics presented oral testimony at the public hearing.

American Medical Association
American Roentgen Ray Society
American Society for Therapeutic Radiology and Oncology (ASTRO)
American Society of Nuclear Cardiology
American Society of Radiologic Technologists
Conference of Radiation Control Program Directors
Council on Radionuclides and Radiopharmaceuticals (CORAR) & Du Pont Pharmaceutical
Diatech Inc.
DuPont Merck
Health Physics Society
Mallinckrodt Medical Inc.
McElroy, Norman L.
National Electrical Manufacturers Association
New York Hospital-Cornell Medical Center (NYH-CMC)
North Shore University Hospital (NSUH)-Cornell University Medical College
Radiological Society of North America
Sloan-Kettering Memorial Cancer Center
Society for Nuclear Medicine
State of Arizona Radiation Regulatory Agency
State of Florida Department of Health and Rehabilitative Services
State of Illinois
State of Kansas
State of Kentucky
State of New York Department of Health (NY-DOH)
State of North Carolina Department of Environment, Health and Natural Resources
State of Texas Department of Health
State of Utah Department of Environmental Quality
State of Washington Department of Health
Syncor
Wenatchee Valley Clinic

QUESTION SUMMARIES

Question 1 (N = 34)

Does the current regulatory structure pertaining to the medical uses of ionizing radiation provide adequate safeguards to protect the public's health and safety? If not, how might the respective roles of various Federal and State authorities be revised to assure greater patient safety and cost effectiveness?

In response to this question we received 34 replies: 18 from professional associations, societies, and industry; 10 from states; and 6 from miscellaneous

sources. There was widespread opinion that the current regulatory structure pertaining to the medical uses of ionizing radiation adequately protects the public's/worker's health and safety (ABNM, NEMA, Syncor, ACR, Mallinckrodt, CORAR, Texas, New York). Some believe it is adequate because "it is incidental to insuring public health and safety. Professional pride, peer pressure and legal implications of errors are more important factors than regulations" (AAPM).

Others asserted that the existing regulatory structure protects the public health and safety "with a level and degree of regulation that is often excessive to achieve the desired goal" (RSNA). The Society for Nuclear Medicine stated that the existing structure is *not* useful for protecting the public. "Excessive regulations are proving unnecessary, prescriptive, expensive and prohibitively burdensome to hospitals and physicians in private practice" (SNM). In view of these statements the American Roentgen Ray Society suggestion appears reasonable: "Validity of regulatory requirements must be re-evaluated and changed as appropriate."

The primary concern about the adequacy of the regulations focused on excessive paperwork, cost effectiveness, diagnosis and treatment of disease (ACNP, Illinois, RSNA, North Shore Hospital, Mallinckrodt, SNM). "Licensees are faced with ever increasing regulations that are costly to implement. NRC's licensing and annual fees have increased 1000% since Congress turned over full budget authority to the NRC through the collection of user fees … medical licensees are restricted in their ability to recoup costs" (ACR).

"In diagnostic nuclear medicine even a gross error has virtually no practical possibility of inducing a perceptible adverse health effect in the affected patient. The current regulatory structure simply does not reflect this reality. Burdening health care providers with excessive regulation and diverting the time and efforts of highly compensated professional and technical personnel from patient care to regulatory compliance causes health care costs to escalate and impedes the delivery of effective care"(NYH-CMC). "… [O]ften NRC's licensing requirements exceed the regulations promulgated in the CFR [Code of Federal Regulations] and add additional expense … large fees are not commensurate with services rendered" (SNM). The Society of Nuclear Medicine believes that "there is a loophole in the existing requirements under the Administrative Procedures Act that allows the NRC to bypass an accurate cost/benefit analysis for new regulations affecting medical licensees."

The distinction between diagnostic and therapeutic applications was noted in several instances. "The regulatory framework is inadequate relative to therapeutic applications"(NYH-CMC). In addition, the American College of Nuclear Physicians noted that the public is adequately protected but the patients are less so. "The patients are not as well protected as is desirable, but the situation is different with different types of ionizing radiation in medicine."

Several respondents stated they favored a single federal agency with authority to regulate ionizing radiation in medicine. They argue that a single agency

would be more cost effective and would assure greater patient/staff safety (NEMA, ABR, Washington, New York, North Carolina; see synopsis of question #3 for elaboration of this issue).

Although some respondents noted inconsistency among the states, several other respondents believed that the regulatory responsibility for ionizing radiation in medicine should be shifted to the states or the states in conjunction with the federal government. "A uniform regulatory structure that would be more cost-effective and assure greater patient/employee safety would be achieved by state regulation and inspection of *all* sources of ionizing radiation based on conformity with minimum basic national regulatory safeguards" (ABNM). "Federal standards need to be developed in full consultation with the states and involvement by the public and regulated community. [A] State agency should have flexibility to develop a regulatory program consistent with federal standards which reflects local needs and conditions" (New York).

A different approach was proposed by the American College of Medical Physics (ACMP). The ACMP suggested that regulatory agencies should revise their programs to require adequate facility design for safe operation, adequate staffing with required qualifications (certification/licensure), and standards of practice following established QA protocols developed by relevant professional/scientific organizations. ACMP proposes that periodic inspections should be performed by a small team of experts to evaluate both physical and clinical aspects of the program and that "the regulatory agency" should require compliance with the recommendations of the site team. ACMP did not specifically identify the regulatory agency. Finally, the ASRT stated that the regulations need to address the credentialing of technologists.

A few respondents stated that NRC's scope of control should not be expanded and in certain instances should be reduced (Du Pont Merck, Illinois, Washington, Florida) or that insufficient data are available to justify fundamental changes in the structure (ASTRO). Illinois asserted that the federal agencies should respect efforts of the states and professional societies in regulating the practice of medicine and that the federal government should only require each state to have a radiation regulation program that has all the basic components necessary to implement the equivalent of the model state statutes provided by the CRCPD licensing state program. The American Medical Association recommended that the NRC work in conjunction with the private sector and other government agencies.

Various respondents noted the omission of federal requirements for x-ray programs that include linear accelerators (Kentucky).

The majority believed that the existing regulatory structure adequately protects the public's health and safety, but there was sentiment that the cost/benefit ratio is disproportionate and should be reevaluated. Opinions varied as to whether a single federal agency should regulate all of ionizing radiation in medicine or whether this responsibility should be transferred to the states under a national set of performance standards (see question #3 for further discussion).

Question 2a (N = 21)

How does the current regulatory framework—as it applies to ionizing radiation in medicine—affect the practice of medicine?

In response to this question we received 21 replies: 16 from professional associations, societies, and industry; 3 from states; and 2 from miscellaneous sources. Although there was no singular answer to this question, there seemed to be widespread agreement that the current regulatory structure was, as one association explained, "very expensive, time-consuming and inhibitory" (ABNM). As one commentator explained, "By burdening health care providers with excessive regulation and diverting the time and efforts to highly compensated professionals and technical personnel from patient care to regulatory compliance, health care costs escalate and the delivery of care is impeded" (NYH-CMC). Others asserted that various prescriptive regulations deprived physicians of the flexibility and judgment that they needed to optimize their practice. Another observation was that high licensing fees might inadvertently drive people out of the nuclear medicine business. A commentator from the Illinois Department of Nuclear Safety declared: "Clarification of jurisdictional boundaries and reciprocal recognition of authority between agencies would be a good start in eliminating duplicative paperwork requirements. This would allow medical professionals more time to practice medicine."

Question 2b (N = 30)

What is your opinion of the revised quality management rule for misadministrations and the new reporting requirements? How would you change it? What suggestions would you make regarding tracking/preventing misadministrations? Are the NRC's definitions of misadministrations on target?

In response to this question we received 20 replies: 11 from professional associations, societies, and industry and professional societies; 6 from states; and 3 from miscellaneous sources. In contrast to question 2a, for which there appeared to be a consensus regarding possible overregulation, answers to question 2b revealed a considerable divergence of views. Whereas many respondents expressed a favorable view of the new QM rule and reporting requirements, others were not nearly so sanguine. A similar difference of opinion was generated in response to the question regarding the new definition of misadministration.

Some of the more notable comments were as follows: "The 'new' rules for reporting have downplayed the importance of any errors except those involving iodine and therapy. The result has been to create a 'doesn't matter' atmosphere that leads to a lack of concern for care in other areas of operation" (AANC). "The problem is not in the rule, but the way NRC is enforcing it" (AAPM). "The revision to the quality management rule made the rule a little more palatable but not necessarily acceptable nor necessary. … The approach used by the NRC with its quality management and inspection program is overly prescriptive and

does not lend itself well to the concept of quality improvement which should be at the heart of each institution's program" (ACR). NRC's misadministration reporting requirements "seem unreasonable in an area of medicine where the misadminstrations [rate] is less than 0.1%" (ARRS). One of the more insightful comments came from the National Electrical Manufacturers Association (NEMA): "The revised Quality Management Rule did not generate many time-consuming procedures. These procedures were in fact those already found in good operating programs prior to the implementation of the new QM rule. … The new definition of 'misadministrations,' concomitant with the new QM rule, is now more realistic. However, in our view, the Quality Management Rule, even as amended, will not serve to reduce 'misadministrations' since the rate of misadministrations for nuclear medicine is extremely low, and is probably at the lowest rate of any modality." Others explained: "The revised definition for a misadministration is an improvement over the previous one. … The reporting requirements are appropriate [and] the implementation of this [QM] rule was uneventful from a radiation safety perspective at a broad licensed facility" (RSNA).

The states were equally divided in their interpretation of the new QM rule and concomitant reporting requirement. "The revised QM rule and reporting requirements for misadministrations are improved by the fact that emphasis is being placed in the more significant events. … NRC's definitions of misadministrations appear to be on target" (Florida). "The quality management (QM) rule was an attempt to fix something that was not broken, and should be repealed" (Illinois). "By deleting the reporting requirement for diagnostic uses of radioisotopes, the regulatory agencies are not able to track trends, such as tracing mislabeled or improper radiopharmaceuticals back to a nuclear pharmacy" (Texas). "While the Quality Management rule codifies a concept that is already fairly well established, it also adds a significant paperwork burden for all licensees, keeps the regulator busy reviewing the accumulated paper rather than evaluating the actual radiation safety practice of the institution, and potentially generates civil penalties which distract the licensee from needed radiation safety improvements. … NRC's definition of misadminstrations is also reflective of the narrow focus of the agency" (Washington).

Question 3 (N = 31)

The Atomic Energy Act of 1954 as amended requires that the Nuclear Regulatory Commission (NRC) regulate reactor-generated byproduct material. Do you believe the act should be amended to require uniform regulation of all ionizing radiation used in medicine under a single Federal agency? If so, which agency? An existing one (i.e., NRC, FDA)? A new one? What role should this agency have vis-à-vis the states?

In response to this question, we received 31 replies: 18 from professional associations, societies, and industry; 8 from states; and 5 from miscellaneous

sources. The majority believes that regulation of all ionizing radiation used in medicine should be uniform. However, this is the extent of the agreement among respondents. The proposals for how uniform regulation could be achieved revealed a spectrum of ideas.

Three respondents said that a new federal agency should be created (one said a new agency within DHHS and one of the three said a new one or the FDA). Three respondents stated that the NRC should retain jurisdiction, and one stated that the NRC should expand its authority to include discrete NARM (naturally occurring and accelerator-produced materials) and potentially accelerators. Two indicated that they preferred the FDA. Four stated there should be a single agency, but did not identify an existing one or state whether there should be a new one. One respondent said responsibility should be split between the FDA and the NRC, with the FDA regulating electronic product radiation and the NRC regulating all radioactive material used in medicine. Four indicated that the states should assume responsibility, and one of the four said the states should be subject to a national set of performance standards.

Two respondents said the NRC should not be the agency regulating ionizing radiation; one said the EPA should not have the responsibility; and one said that FDA should not be the lead agency. Two respondents indicated that a single agency is not needed, and one said that if a need is perceived for a lead agency it should not be the NRC. Finally, one proposed to coordinate all radiation regulations, including NRC regulations, within the Executive Branch (e.g., in the National Science and Technology Council via CIRRPC). Another organization proposed to reestablish the Federal Radiation Council.

Thus, it is generally believed that all of ionizing radiation should be regulated by a single agency. "[There are] too many instances in which reactor-generated materials are more stringently regulated than NARM materials" (NEMA). States with adequate resources would have the right to implement and enforce combined regulations under provisions similar to the Agreement State provisions of the NRC. Licensing, inspection and enforcement would come within the authority of these Agreement States, but they would have to adhere more closely to regulations promulgated by the new agency. The new/ federal agency would still carry oversight responsibility (NEMA).

There was some concern that creating a single agency to address all of ionizing radiation may not be the appropriate solution. For instance, Syncor did not believe that providing the NRC with authority to regulate the medical uses of other forms of ionizing radiation will necessarily improve the quality of regulation, or better effectuate the goal of regulation.

"Relative harm to the public should be measured prior to establishing regulations. Existing voluntary efforts should be analyzed and a determination made as to the cost effectiveness of adding further regulations. Fiscal analyses of where the public's money would be best spent to protect the public should be made prior to the adoption of future regulations" (ACR).

"It would be beneficial for one organization to have regulatory power for all sources of internally administered ionizing radiation. Placing all ionizing radiation (external and internal) under one agency would be a mistake. … Issues [surrounding] externally administered radiation are different and tend to be device related far more than internally administered radiation" (RSNA).

Finally, one group believed that the regulation should be expanded to incorporate nonionizing radiation. "Have a single agency … include the regulation of practices that involve nonionizing radiation used in medicine, such as ultrasonography and MRI [magnetic resonance imaging" (ASRT).

There was a cry for uniformity. What specifically ought to be uniform was not entirely clear. There also appeared to be no consensus as to how that uniformity is to be achieved.

Question 4 (N = 28)

Do you believe that the current regulatory framework pertaining to the medical uses of ionizing radiation reflects the actual risks associated with various diagnostic and therapeutic applications?

In response to this question we received 28 replies: 18 from professional associations, societies, and industry; 7 from states; and 3 from miscellaneous sources. There was widespread consensus that the current regulatory framework is too elaborate, expensive, and time intensive relative to the actual risks associated with diagnostic applications. "Clinical benefits of radiation exposure greatly outweigh the risks" (HPS). Several respondents indicated that the actual risks related to diagnostic applications are many orders of magnitude less than the risks of other treatment modalities, such as administration of drugs, anesthesia, and medical/surgical procedures that are unregulated: "Misadministrations occur at much higher rates in these disciplines, but since these areas do not have attending regulatory agencies the degree of their regulation is much less" (ACR). "Patients perceive that risks that are important enough to get the federal government involved are greater than risks which do not require any government agency oversight or regulation" (ABNM). "Compared with therapeutic and diagnostic interventions in traditional medicine, the adverse events in nuclear medicine are few and of limited medical consequence" (Syncor).

Several respondents noted that the regulatory structure should distinguish between the risks of therapeutic and diagnostic applications in ionizing radiation. "Levels of radiation received by a patient undergoing diagnostic procedures are significantly lower than the levels for therapeutic procedures. The current level of regulation, however, is virtually the same" (Syncor). "The current framework reflects the risk associated with therapeutic uses but overestimates and overcontrols diagnostic uses" (ARRS).

Risk was also addressed in the context of education and training of personnel involved in performing diagnostic and therapeutic applications of radiation in medicine. It was noted that the existing regulatory framework does not "address

risk factors involved in utilizing uncertified individuals to perform diagnostic and therapeutic applications involving radiation" (ASRT).

One individual believed that the key risk associated with the medical use of byproduct material is unretrieved brachytherapy sources. Texas and Illinois indicated that accelerators and diagnostic x-ray are unregulated at the federal level. They are not covered under misadministration requirements or in training standards for users. Kansas observed that the rules pertaining to cobalt-60 teletherapy and accelerators are very different despite the fact that both are capable of delivering doses that could cause serious acute injuries.

Question 5 (N = 19)

Are your patients informed about the potential risks associated with medical procedures involving ionizing radiation? If yes, how? If not, why not?

In response to this question we received 19 replies: 15 from professional associations, societies, and industry; 2 from states; and 2 from miscellaneous sources. There was widespread consensus that patients are informed verbally and via a written consent form (requiring their signature) regarding radiation hazards of therapy procedures by the physician and/or other personnel. The same is true in some cases regarding ionic contrast medicine. Regarding diagnostic procedures, patients are often informed verbally by the technologist or physician. "In some institutions, the patient is not informed about potential risks for diagnostic procedures as the risk is judged to be too small" (ABNM, AAPM), "and the anticipated medical benefit is so large as to make such discussion unnecessary and potentially counterproductive" (NYH-CMC). However, particular attention is paid to women of childbearing age who might be pregnant or lactating. Signs about potential risks to the fetus are posted and efforts are made to ascertain a woman's pregnancy status.

A few respondents indicated concerns regarding inadequate information. "In general patients are getting limited and sometimes inadequate information to understand the potential risk of radiation" (ARRS). "[We have] no direct patient contact; amount of information provided regarding risk is dependent on medical facility. Our members indicate that patients may not be [getting] adequate information for a variety of reasons that include lack of knowledge that is available. Our philosophy is that all patients deserve to be informed of all risks for any procedure performed on them" (ASRT).

Note: Florida stated that its regulations do not require that all patients be informed about the potential risks associated with medical procedures involving ionizing radiation. Information is provided as requested by patients in most cases.

Question 6 (N = 27)

In your experience, has the evolution of radiation protection standards helped to improve patient safety and welfare? Has it influenced staff safety and welfare?

In response to this question we received 27 replies: 18 from professional associations, societies, and industry; 6 from states; and 3 from miscellaneous sources. There was a general sentiment that the evolution of radiation protection standards (as distinguished from regulations) based on recommendations of national (, NCRP) and international (International Commission on Radiological Protection, ICRP) bodies have helped to improve both patient and staff safety and welfare. Requirements regarding training of technologists and other individuals using ionizing radiation have improved patient and worker safety (Illinois). An excellent example of improved patient safety and welfare may be the change in the last 15 years in the practice of mammography (Kansas, Texas, NY-DOH).

The incorporation of NCRP recommendations has also influenced the practice of radiation safety procedures (ACMP). In particular, 10 CFR Part 20, relative to staff safety was cited, specifically the ALARA (as low as reasonably achievable) program as one that has "heightened staff awareness of the level of accumulated personal radiation exposure" (NEMA, Syncor).

Although it was generally believed that the evolution of radiation protection standards improved both patient and staff safety and welfare, the "regulations promulgated to achieve these standards are collectively excessive" (NYH-CMC). "Efforts to drive down occupational exposure limits have not resulted in improved occupational health but have resulted in substantial increases in compliance costs" (Health Physics Society). "Regulatory agencies may be crossing the line between requirements that result in an increase in paperwork without an actual safety benefit" (Illinois).

Question 7 (N = 26)

Who should bear the ultimate responsibility for devising appropriate quality assurance programs? Professional associations such as JCAHO, ACR, AAPM, etc.? State agencies? Federal agencies?

In response to this question we received 26 replies: 18 from professional associations, societies, and industry; 5 from states; and 3 from miscellaneous sources. Although the response was not unanimous, there appeared to be overwhelming consensus that the various professional associations should be entrusted with the task of devising appropriate quality assurance programs.

"I believe a professional organization such as ACR or AAPM should develop guidelines for QA programs with oversight of the programs the responsibility of JCAHO. I do not believe any federal [agency] should devise the programs" (AAPM). "It is essential that quality assurance programs be based within appropriate professional associations … state and federal agencies should establish

minimal regulations to protect the welfare of the public" (ARRS). "We believe that model QA programs should be developed by professional associations" (ASRT). "The Boards of Medicine and the professional associations, with input solicited from the appropriate state and federal agencies, should bear ultimate responsibility for devising the appropriate quality assurance program" (CORAR). "The responsibility for the development and implementation of quality assurance programs must lie with professional organizations" (HPS). "The ultimate responsibility belongs with the specialty societies. … Federal agencies should adapt these programs when the ultimate authority must reside with government" (RSNA).

As stated above, not all respondents agreed that professional associations were suited to this task, however. NEMA asserted: "We believe a federal agency, or state agencies in agreement with the federal agency, should bear this responsibility. However, in the course of its development, the federal agency in question should rely heavily upon the input from professional associations." NEMA continued: "Professional organizations cannot enforce, therefore they do not fit these [i.e., the need to assure an effective QMP] criteria." This view was reiterated by the Florida Department of Health and Rehabilitative Services: "The state agency must use its own resources as well as those of federal and professional agencies an institutions to field and adequate control program which included a quality assurance/management component."

Question 8 (N = 15)

If applicable, what kind of QA program do you have in place? Upon whose expertise did you rely when devising it? How is it working?

In response to this question we received 15 replies: 14 from professional associations, societies, and industry; and 1 from miscellaneous sources. All 15 respondents acknowledged having a QM program in place. Most stated that their programs were based on a combination of sources including model professional guidelines, JCAHO, in-house expertise, and various state and federal requirements. "We have a continuous QA improvement program patterned on the requirements of JCAHO. We developed it using our in-house expertise" (AAPM). "Most programs have QA programs in place that embody the essential components for the current NRC QM rule. … Expertise used to devise is quite varied and includes internal staff, medical radiation physicists, quality improvement/management personnel, etc." (ABNM). "Our programs are based on several documents and protocols written and published by the AAPM, ACMP, ACR, and ASTRO. The program was devised by the medical physics division and with input from the staff physicians. The person-hours and the required paper work to maintain a good QA/QMP program have certainly increased. We have not seen any noticeable benefit to the patent, staff or members of the general public in terms of reduced risk" (ACNP). "We rely on the expertise of these specialists in establishing, updating and maintaining our radiation safety program.

The program seems to be working well. In terms of quality assurance within the facility, we utilize a complex of professional standards and programs, JCAHO reviews, and government requirements to ascertain a proper mix for ongoing quality improvement efforts" (ACR). "The institution and department QA programs [are] based upon published guidelines and professional associations and in compliance with state and federal agencies. They were developed by adhering to in-house expertise. They seem to be working well" (ARRS).

Question 9 (N = 17)

The 1981 Consumer-Patient Radiation Health Safety Act provides minimum standards by the Federal Government for the accreditation of education programs for persons who administer radiologic procedures and for the certification of such persons. Do you adhere to these standards? Are they effective?

In response to this question we received 17 replies: 11 from professional associations, societies, and industry; 5 from states; and 1 from miscellaneous sources. Many of the respondents were not aware of act's existence. Of those who were, most seemed to think that, at best, it had a minor impact. As the American Society of Radiologic Technologists explained: The act "laid the groundwork for what could have been a step in the right direction for reducing risks and improving cost effectiveness in the use of ionizing radiation by setting minimum standards for the certification of persons who administer radiologic procedures. However, because the standards set in the Act were made voluntary, this Act became a totally insufficient piece of legislation" (ASRT). Other respondents commented on the volatile political issue regarding certification and licensure: "NRC has been subject to political pressure from various medical lobbying groups whenever it has attempted to rigidly enforce the requirement for certification of education of various professional groups. Exceptions made in the area of nuclear cardiology are but one example" (MS-KCC). Despite this issue, many acknowledge the need for such certification. "In order to assure proper standards, all health practitioners should be licensed, including nuclear medicine technologists. … In New York we have no licensing for technologists in Nuclear Medicine. New York State requires certification when a technologist is responsible for radiopharmaceutical administration. Licensure would assure attainment of an appropriate level of training" (NSUH).

Particularly illuminating were the responses from various state radiation agencies: "The State of Florida adheres to the Radiological Technologist Certification Act which we consider effective. It states that all educational programs for certified radiological technologists [must] include documentation of accreditation by the American Medical Association Committee on Allied Health and [must be] currently approved by the United States Department of Education." "Illinois requires minimum standards of education, including continuing education, for persons who perform medical radiography, nuclear medicine technology

procedures, or administer radiation therapy. The standards and requirements for training prescribed by Illinois' statute and regulation are certainly equal to, and in most cases exceed, those standards suggested by the Act" (Illinois). The Illinois respondent went on to explain that "there are still 21 states, with regard to medical radiography, that have made no progress during the past 13 years in implementing the minimum standards for training and education described in the Act. In addition, there are still 35 states which have no requirements for technologists who use radioactive materials and perform nuclear medicine procedures. While the Act describes minimum standards, there has been little guidance provided to the states on implementation of these standards."

Question 10 (N = 24)

What, if any, Federal agency should be responsible for establishing educational standards for accreditation regarding the medical use of ionizing radiation? NRC? FDA? Other? How should the quality of the education programs be judged? What criteria should be applied?

In response to this question we received 24 replies: 16 from professional associations, societies, and industry; 5 from states; and 3 from miscellaneous sources. On this question, there was no consensus. Answers typically fell into one of two categories: (1) There should be no federal involvement in this issue. (2) Federal involvement is appropriate but determining which agency is no simple task.

Most of the professional associations offered the first response. In place of federal oversight, they argued instead for industry self-regulation. "There is already a complete working mechanism for the review, accreditation and periodic re-review of education programs for radiological technologists, and radiation therapists. All that would be necessary is to require all individuals using ionizing radiation for medical uses to either be a licensed health care professional or a graduate of an accredited program" (AAPM). "Government agencies should not have responsibility for developing educational standards, standards for accreditation of training programs, or certification of qualifications (competence) to practice medicine using ionizing radiation. This should be the responsibility of professional organizations" (ABNM). "We do not think that any Federal agency should be directly responsible for establishing educational standards for accreditation regarding the medical use of ionizing radiation. This should be the assumed responsibility of established professional/educational/scientific organizations. … Educational programs should be evaluated by accreditation bodies which may operate under the auspices of a Federal agency" (ACMP). "No Federal agency should be involved with this. … Professional accrediting organizations exist to accredit programs, and this all that is needed. … For those who do not possess certification by an acceptable professional group, the State can offer an examination, as is done in California" (ACNP). "Neither agency [FDA or NRC] is well-equipped to make this type medical decision and neither should be

called on to do so. The states should continue to play the most significant role in determining what are the appropriate education and training criteria for licensed professionals practicing in their states" (ACR). "We believe that there would be no great need for a federal agency to attempt to replace the existing education standards, criterion and judgments already established within the medical radiologic community. Instead, a federal agency should work with private entities involved in curriculum development and certification standards" (ASRT). "The establishment of educational standards for accreditation regarding the clinical use of ionizing radiation is best handled by the educational committees of the various interested professional organizations" (NEMA). "[E]ducational standards should remain the province of the appropriate credentialing bodies for externally administered ionizing radiation for diagnostic purposes and appropriateness of use should be determined by the market place" (RSNA). "No federal agency should establish educational standards for any medical practice. Such standards should be established, supported, and accredited by professional peers. Federal agencies may set minimum standards for recognition of training and experience for entry level professionals based on input from the profession. An effective example of this profession/regulatory interplay is the development of the NRC's proposed Authorized Nuclear Pharmacy Rule" (Syncor).

Not all professional societies and medical representatives subscribed to the notion that the federal government should play no role in the accreditation process. "[G]overnmental agencies should defer to national professional organizations in devising educational standards. As in insuring uniform regulation of all ionizing radiation used in medicine, in the area of technical training, I believe a single federal agency, preferably the NRC, should probably be responsible for devising educational standards" (NYH-CMC). "The NRC is the logical regulating body to set minimal federal guidelines for training practitioners regarding radiation and radiation safety. However, the professional associations and accreditation bodies must have responsibility for establishing quality programs and local committees for local implementation" (ARRS). "Minimum standards for education and accreditation regarding the medical use of ionizing radiation can be established by the Nuclear Regulatory Commission. Individual states should have the right to adopt more strict criteria for education and accreditation programs if they so desire" (ASTRO).

The state responses differed markedly from the professional associations. Of those who responded, most seemed to think that the Department of Education should play a role in the certification process. "The U.S. Department of Education with appropriate technical input from other agencies such as the NRC and the FDA should be responsible for establishing educational standards for accreditation" (Florida). "The Department of Education, through its Council on Allied Health Education and Accreditation (CAHEA), established an effective means of accrediting such programs. This process has been in place for many years and has been quite effective where it is used. … The standards, and related processes, are well established and their use should be encouraged"

(Illinois). "The US Department of Education has considerable experience in credentialing professional bodies to accredit educational programs. It is appropriate for that department to continue this function."

Question 11 (N = 16)

How are personnel under authorized users supervised/trained in your facilities? How should they be? How are users trained in applications of new technology? What kind of ongoing training is provided? Should recertification be by test or evidence of continued education?

In response to this question we received 16 replies: 13 from professional associations, societies, and industry and 3 from the states. The overwhelming number of respondents agreed that continuing education and in-house training were the best means of assuring a competent work force. A smaller number suggested that testing was also important. And an even smaller number argued that there was a role for federal authorities in this broad area. As the AANC representative explained: "Regulatory agencies must look at the documentation of training, even if the training is part of a residency program, and determine that the regulatory requirements have been met" (AANC). The majority of comments, however, were of the following type: "The process of 'recertification' is best accomplished through well documented continued education" (ABNM). "Whenever new technology is introduced a special training is conducted by application specialists supplied by the manufacturer. Further in-house on-the-job training is provided by the medical physicist or equipment specialist who may have attended a special course at the factory" (ACMP). "I believe that recertification should occur by documentation of CME [continuing medical education]" (ACR). "Recertification could best be done as a combination of continuing education and testing" (ARRS). "We believe that an individual working in any aspect of medical radiologic science should demonstrate minimum certification criteria with regard to an accredited education, practice experience and successful passage of a certification examination" (ASRT). "It is not clear what the optimum approach to re-certification is, but I feel that periodic testing, especially of highly experienced practitioners, would be strongly resisted and may well be unreasonable" (NYH-CMC). "Recertification can be accomplished by either testing or continued education" (Florida). "Illinois believes that the evidence of continuing education is adequate for re-certification of technologists at this time. The Department is aware of no medical profession or allied health occupation that is currently required to pass a test for re-certification" (Illinois).

Question 12 (N = 19)

What are your other concerns regarding the regulation of ionizing radiation in medicine?

In response to this question we received 19 replies: 12 from professional associations, societies, and industry; 6 from states; and 1 from miscellaneous

sources. Given the open-ended nature of this question, it was surprising to see that so many answers reflected a similar concern—namely, a preoccupation with what many considered to be overregulation and the duplication of various regulations regarding the uses of ionizing radiation. A smaller number focused on the costs attached to these regulations—particularly the required paperwork. "The cost of regulation of radiation in medicine is high and the benefits are low. Radiation in medicine is over-regulated when the amount of risk to the public is considered" (AAPM). "Under the current system, we divert a tremendous amount of our limited resources to protect ourselves against ionizing radiation. Ultimately, we are less safe because monies are not available to protect ourselves against the much larger risks that affect our health" (ABNM). Relative risk between medical disciplines should be measured and considered prior to adopting rules as should relative harm to the public. Voluntary efforts need to be considered more fully. Unsuccessful regulations should be abolished, and financial analyses should be employed to determine where money is best spent (ACR). "The needless over-regulation of medicine has become cumbersome, difficult for patients, and more expensive at no benefit to the patient or to the regulating agencies beyond the apparent self-serving need to perpetuate multiple agencies with ambiguous role and scope definition, unnecessary redundancy and predictable excessive delays, and increased costs" (ARRS).

In addition to comments of this nature, others spoke of the need for a single federal agency to deal with all issues relating to ionizing radiation. "While a 'national coordinating role' such as is provided by the CRCPD is preferred, the formation of a single federal 'public health' agency would be a reasonable approach to effectively resolving the issue" (Washington). And others, still, urged caution: "Although we advocate some changes to the current system, we would caution those that propose changes beware of the 'pendulum' effect, where we go from having too much regulation to having no regulation at all" (Illinois). "The rush to correct a problem has in the past created more problems than it solved. Care needs to be taken that anecdotal data and poor science are not substituted for careful evaluation of real data and development of a sound response" (Kansas). "We must assure that public safety is not sacrificed in lieu of cost savings" (ASRT).

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Quality Management Technical Panel

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K

The Linear, No-Threshold Model

ADOPTION OF THE LINEAR, NO-THRESHOLD MODEL

A series of developments from 1954 through 1972 marked the transition to adoption of the linear, no-threshold model as a predictive model of radiation injury in exposed populations. In 1954, the National Council on Radiation Protection (NCRP) issued new guidance on radiation protection in which the tolerance dose was replaced by a new concept, the *maximum permissible dose* (MPD) (NCRP, 1954). Implicit in the MPD concept was rejection of the concept of tolerance dose and establishment of the idea of "acceptable risk" at low levels of exposure.

Divided Scientific Opinion, 1958–1966

In 1958 the United Nations Scientific Committee on the Effects of Atomic Radiation issued its first report on the effects of radiation exposures in humans (UNSCEAR, 1958). This report estimated the risk of adverse effects of low-level radiation exposure using both a no-threshold and a threshold model of radiation risk. The report included the following statement:

> Present knowledge concerning long-term effects and their correlation with the amount of radiation received does not permit us to evaluate with any precision the possible consequence to man of exposure to low radiation levels. Many effects of radiation are delayed; often they cannot be distinguished from other agents; many will develop once a threshold dose has been exceeded; some may be cumulative and others not; and individuals in large populations or particular

> groups such as children and fetuses may have special sensitivity. These facts render it very difficult to accumulate reliable information about the correlation between small doses and their effects either in individuals or in large populations. (UNSCEAR, 1958, p. 42)

With respect to radiation-induced leukemia identified in the Japanese populations exposed to atomic radiation well above the low-dose limit, UNSCEAR concluded that the threshold and no-threshold models of radiation injury had equal validity. This conclusion was contested by the Committee on Pathologic Effects of Atomic Radiation of the National Academy of Sciences/ National Research Council (NAS/NRC), which stated unequivocally that "a considerable body of experimental evidence" favored nonlinearity and hence presumably a threshold, and urged that nonlinear relationships between dose and effect should be given greater attention (NAS/NRC, 1959). The following year, the short-lived U.S. Federal Radiation Council (FRC, see Appendix G) observed that the linear, no-threshold model merely presented an extrapolated upper limit of radiation risk for low exposure levels (FRC, 1960). In UNSCEAR reports in the 1960s, the committee emphasized that extrapolation of the linear, no-threshold curve provided an upper limit to the risk of low-level exposures (UNSCEAR, 1962, 1964). This position was endorsed by the International Commission on Radiological Protection (ICRP, 1966).

Joint Committee on Atomic Energy Hearings, 1957–1960s

Meanwhile, in the late 1950s, the congressional Joint Committee on Atomic Energy (JCAE) conducted hearings that had a major influence on the thinking of both the scientific community and the public with regard to radiation hazards. The hearings began in 1957 with an inquiry into the nature of radioactive fallout from weapons testing and its possible effects on humans (JCAE, 1957). Testimony from scientific experts addressed but left unresolved the issue of the most appropriate model for estimating the degree of hazard at low exposure levels. The JCAE addressed this issue again in its 1959 hearings (JCAE, 1959) and again left it unresolved. However, the hearing report (p. 59) included testimony by K.Z. Morgan, Director of Health and Human Physics at the Oak Ridge National Laboratory, claiming that certain bioeffects, including genetic mutations, leukemia induction, and life shortening, occur without a threshold dose. Also influential was the testimony of E.B. Lewis, professor of biology at the University of California, San Francisco, who strongly supported the linear, no-threshold hypothesis as a model for radiation protection standards. Lewis proposed the concept of protection called "as low as reasonably achievable" (ALARA) (JCAE, 1960). In subsequent hearings over the course of the 1960s, the JCAE moved slowly to the endorsement of the linear, no-threshold model of radiation risk.

The BEIR Report and the Code of Federal Regulations, 1972

In 1964 the NAS/NRC established an advisory committee on the biological effects of atomic radiation (BEAR) to examine issues related to radiation protection, including the shape of the dose-response curve at low doses. The BEAR committee introduced the concept of regulating doses to the population as a way of limiting the effects of radiation on future generations. The BEAR committee was renamed the Committee on the Biological Effects of Ionizing Radiation (BEIR), which issued its first report in 1972 (NAS/NRC, 1972). The 1972 report did not deal with the issue of the shape of the dose-response curve, but it did provide estimates of cancer risk at low doses based on a linear extrapolation from cancer mortality data at high doses in Japanese survivors and other exposed groups. These estimates implied that radiation carcinogenesis does not exhibit a threshold dose, in spite of the absence of confirmatory experimental data.

Also in 1972, the U.S. Atomic Energy Commission (AEC) introduced the ALARA concept (also known as ALAP, as low as practicable) as Appendix I to Title 10, Part 50, of the Code of Federal Regulations. The implication of ALARA is that no threshold exists for adverse radiation effects and that any dose, no matter how small, is potentially injurious to exposed individuals.

These actions of the NAS/NRC and the AEC completed a major transition in the conceptualization of radiation risk at low doses, and they provided a foundation for the evolution of health physics as a discipline devoted to the protection of workers and the public against small doses of ionizing radiation.

WIDENING APPLICATIONS AND CONTINUING DEBATE

Risk-Based Standards for Radiation Protection

In 1977 the ICRP announced its risk-based approach to the establishment of standards for radiation protection (ICRP, 1977). This approach was a highly significant departure from traditional dose-based standards, and it defined the concept of acceptable risk from radiation exposure of workers in terms of the fatal accident rate in so-called safe industries. In taking this approach, the ICRP used extrapolation based on the linear, no-threshold model to estimate hypothetical death rates from radiation-induced cancers among workers exposed to low-dose radiation and compared these hypothetical deaths with real and measurable fatalities in other ("safe") industries. The ICRP also introduced a number of factors to express the risk of partial-body irradiation in terms of the equivalent risk of whole-body exposure. This risk-based approach to standards of radiation protection was refined and expanded not only by the ICRP (ICRP, 1978–1980, 1990, 1991), but also by the NCRP (NCRP, 1987) and by several U.S. regulatory agencies, including the Environmental Protection Agency (EPA,

1987), the Department of Energy (DOE, 1988), and the Nuclear Regulatory Commission (NRC, 1991).

BEIR Reports, 1979–1990

In 1980 the NAS/NRC BEIR committee released a new report (the "BEIR III" report) on the risks of exposure to ionizing radiation. In the report a majority of the committee endorsed a linear-quadratic[1] model of radiation-induced cancer. The report included two "minority opinions," in which one committee member supported a straightforward linear model of cancer induction and another member endorsed a purely quadratic model. This division among the committee members exemplified more general disagreement within the scientific community about the most appropriate way to characterize radiation risk at low doses. It also reflected concern over the growing practice of using dose-response models to estimate hypothetical cancer risks at doses substantially below levels where epidemiological studies have confirmed injury.[2] Two additional BEIR reports were issued after the 1980 report of the BEIR III committee. The BEIR IV report, which addressed the health risks of radon and other internally deposited radionuclides (NAS/NRC, 1988), offered several suggestions for further research that, collectively, called for intensified experimental efforts to characterize the shape of the dose-response curve for long-term health effects at low levels of exposure. The BEIR V report again considered the broad topic of adverse health effects from exposure to low levels of ionizing radiation (NAS/NRC, 1990). As in previous reports, the committee noted the failure of epidemiological studies to demonstrate hereditary effects in humans exposed to low radiation levels. Nevertheless, the committee confirmed previous estimates of radiation-induced genetic risk in humans, and computed a mutation-doubling dose of 1 Sv in agreement with the range of 0.2–2.0 Sv of BEIR I and 0.5–2.5 Sv of BEIR III. There was, however, a significant change in the BEIR V estimates of cancer risk from radiation compared with earlier BEIR reports. The new

[1] The linear-quadratic model predicts that the risks of radiation injury at low-level exposures are less than those predicted from a linear extrapolation of risks associated with high dose exposure levels.

[2] The BEIR III (NAS/NRC, 1980) report offered several important specific observations. The report noted that it was unknown and probably not determinable whether dose rates on the order of 1 mSv (millisievert) per year, on the order of dose rates from background radiation, were detrimental to people. The report concluded that data presented by Sternglass (1968) and others that purported to show an increased incidence of cancer in populations exposed to low doses were the result of flawed studies. The BEIR III committee recognized that different human genotypes may confer different degrees of cancer risk for a specific dose of radiation, and that developmental effects from radiation exposure in utero may exhibit a threshold dose. Finally, the report suggested that the linear, no-threshold model of radiation risk provided the best estimate of genetic risk.

estimates were determined with the linear, no-threshold model, yielding a threefold increase in the risk of solid tumors and a fourfold increase for leukemia. Although the committee did not consider the rate of dose delivery in its estimates of cancer risk, it proposed a Dose Rate Effectiveness Factor (DREF) which, if applied, would reduce the lifetime cancer risk by a factor of two or more if the radiation were delivered over a protracted period.

Scientific Studies, 1992–1994

Recently published articles addressing the linear, no-threshold model include those of Land (1993) and Peterson (1993). Land offers a critique of the model's foundation in epidemiological data. Peterson (1993) presents a tabular representation of the evolution of the liner, no-threshold extrapolation to establish an upper limit of radiation risk. He traces the evolution from the postulate that every dose, no matter how small, has an associated risk of ill health, through various steps until the final unequivocal statements are reached that radiation follows a linear, no-threshold dose-response relationship, and that all radiation exposure is unsafe.

Other recent reports that bear on the issue of extrapolating risks from high dose to low-dose exposure are several reports that directly address mechanisms of response to low-dose exposures. For example, one-third of the most recent UNSCEAR report is devoted to adaptive responses to radiation in cells and organisms (UNSCEAR, 1994). Finally, a recent international meeting in Kyoto was devoted to examining evidence for biological defense mechanisms in response to low-dose exposures to ionizing radiation (Sugahara, et al., 1992).

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Separate Statement

Robert S. Adler

Having listened to my fellow committee members' views and having carefully reviewed the drafts of the report as they have been circulated, I find myself reluctantly compelled to voice disagreement with several of the report's findings and recommendations. My disagreement stems from my belief that several of the committee's recommendations lack supporting evidence and constitute unwise public policy.

THE COMMITTEE'S CHARGE

As noted in the Preface to the committee report, several events prompted the Nuclear Regulatory Commission (NRC) to ask the Institute of Medicine (IOM) for an independent review and evaluation of the NRC's Medical Use Program. These events included a fatal radiation incident in Indiana, Pennsylvania, and a series of newspaper articles in the Cleveland *Plain Dealer* on the hazards of radiation medicine. In addition, during discussions between the NRC and the IOM, Senator John Glenn held a highly critical hearing on the NRC's regulation of nuclear medicine. These events combined to create doubts about the vigor and effectiveness of the NRC's Medical Use Program.

I think it important to keep the original concerns behind this study in mind when reviewing the committee's findings and recommendations. Among other things, we were asked to determine whether the NRC adequately protected public health with respect to medical radiation. In my judgment, our findings, which are critical of the NRC's efforts, fail to address this question directly. Nowhere do we state clearly and unequivocally, as we should, that the NRC does adequately protect the public's health. We owe the NRC and its critics a clear response

indicating that with respect to the specific incidents that prompted the establishment of our committee, we found no deficiencies in NRC rules or procedures that led to these regrettable occurrences. Practitioner error and aberrational circumstances caused the problems. Short of the draconian step of stationing NRC inspectors in the facilities involved, however, there really was no way that the NRC could have prevented them from happening or could have resolved them more effectively once they occurred.

As far as I can tell, I do not make this point in dissent. There seemed to be complete unanimity among committee members that the accusations of incompetence and timidity directed against the NRC are unfair and misplaced. To the contrary, my colleagues have concluded the exact opposite of these accusations. They insist that the NRC, if anything, is too aggressive and too intrusive in dealing with nuclear medicine. Not only do I disagree with this conclusion, I feel it important to emphasize how difficult it is for a regulatory agency like the NRC to calibrate its regulatory initiatives when it is simultaneously damned for doing too much and for doing too little.[1]

RISKS OF IONIZING RADIATION IN MEDICINE

Ionizing radiation carries both risks and benefits. I have little doubt that ionizing radiation both in its diagnostic and therapeutic uses carries great benefits. Although I believe that the report describes the benefits associated with ionizing radiation, I remain concerned that the report does not detail the potential risks of radiation medicine as thoroughly as it might. I grant that we do not know with certainty the extent, if any, to which radiation medicine causes harm. However, I believe it critical not to dismiss the potential harm that inappropriate use or misuse of this technology presents. Not every concerned voice that is raised about radiation belongs to a cancerphobe, a Luddite, or an ideologue. Given the devastation that cancer causes in the United States—striking roughly 1 million persons and killing roughly 500,000 annually—it is critical that great care be taken with anything, such as radiation, that could potentially cause cancer. It may be that we overdo the regulation of medical radiation compared to other risks, but there are real concerns that need to be addressed.[2] Moreover, the solution to

[1] A number of committee members work in settings regulated by the NRC. They have shared their frustrations about the NRC with me and I have found a number of their comments helpful. As one of the few members who has worked for a regulatory agency, I have tried with equal concern to explain why agencies like the NRC act as they do. In particular, I have pointed out that agencies must enforce rules uniformly, that is, they must ask for the same compliance behavior from responsible actors as they do from irresponsible actors lest they be accused of "selective and unequal" enforcement. To say the least, this can be annoying to those who feel hassled for what they consider minor infractions when they believe that they are operating in a safe and effective manner.

[2] One might ask, "Where are the bodies?" associated with misuse of medical radiation. The response is that there are lots of bodies afflicted with cancer. Unfortunately, we lack the scientific means to discover which, if any, of them result from the misuse of medical radiation.

overregulation need not be the repeal of a substantial portion of federal authority with respect to the medical uses of ionizing radiation. Rather, a measured approach that mixes adequate regulatory authority with a more moderate enforcement philosophy strikes me as preferable to the one advanced in our report.

COMPARING MISADMINISTRATION RATES AMONG MEDICAL MODALITIES

Our report includes a lengthy discussion of misadministration rates and comparison of those in nuclear medicine to other medical modalities. Although I am open to the possibility that misadministration rates in nuclear medicine are lower than in other areas of medicine, I find the attempts to quantify the relative rates among medical modalities not to be helpful.[3] Although our report acknowledges that in "statistical, clinical, and epidemiological terms, comparisons of the risks inherent in very different health care interventions can be problematic," it fails to emphasize the dramatically different methodologies used to collect data related to medical mistakes.[4] One simply cannot draw meaningful quantitative conclusions from data drawn from such disparate sources.[5]

Moreover, in making the case that misadministration rates in radiation medicine are lower than in other areas of medicine, the report recognizes that one of the essential reasons for these rates has been the existence of NRC regulations. Yet, it then declares that the NRC's medical use regulations can be repealed without significant consequence because the standard of safety can now be maintained through nonregulatory mechanisms such as "improving technology, professional guidelines, training requirements, and institutional quality assurance programs." I remain skeptical. These nonregulatory mechanisms operate

[3] I realize that we were asked specifically by the NRC to assess the "error rates and consequences of the use of byproduct materials in comparison to other medical interventions." One reasonable response to this request that could, and should, have been given is that these data do not permit useful quantitative comparisons.

[4] The data regarding different modalities are derived from a mix of voluntary and mandatory systems. Some involve self-reporting, others involve reviews of medical records, and others involve direct observations. One can readily see how these different approaches would confound meaningful quantitative comparisons.

[5] For example, the NRC data come primarily, if not exclusively, from reporting under its misadministration rule. This is a recent rule, which is unpopular among licensees and which is likely not widely complied with. On this point, our report states that even "if it is assumed that the numbers are underreported by a factor of 10 … this level of 'misadministration' is remarkably low." Based on my experience with underreporting at another agency, the Consumer Product Safety Commission, I think it quite conceivable that the rate of underreporting could be much greater than a factor of 10.

in other branches of medicine—such as anesthesia or blood transfusions—yet none of them produce the same low error rates claimed for radiation medicine, the one highly regulated branch.

FINDINGS AND CONCLUSIONS

I disagree with several findings and conclusions:

The Level of Regulation Compared to the Level of Risk of Reactor-Generated Byproduct Material

Perhaps the key finding of the report is that the level of federal regulation of reactor-generated byproduct material is not commensurate with the risks associated with its medical and biomedical research uses. In making this case, my colleagues make several valid points.

First, ionizing radiation is not regulated uniformly—the NRC addresses only reactor-generated byproduct material, not naturally occurring and accelerator-produced radioactive materials (so-called NARM) or machine-produced ionizing radiation, such as x-rays.[6] Second, byproduct materials are regulated in a more stringent fashion than are other forms of ionizing radiation. As noted elsewhere in this report, the NRC's primary focus is nuclear power in large reactors, and its enforcement approach with respect to nuclear medicine evidently borrows heavily from its comprehensive approach to regulating reactors.

Based on these findings and others, my colleagues urge a consistent approach to the regulation of ionizing radiation. I agree. Unfortunately, the "consistency" my colleagues endorse would end all federal regulation of the medical uses of ionizing radiation. On this, I disagree. I find the case for abandoning all federal regulation of the medical uses of ionizing radiation unpersuasive. As I discuss below, reform, not abolition, makes more sense.

NRC as an Overly Stringent Regulator

Based on numerous discussions with my fellow committee members and on my site visits to regulated facilities, I accept the concern that NRC *enforcement* of its regulations seems inappropriately rigid with respect to the practice of nuclear medicine. Although medicine, like other professions, clearly requires guidelines and standards, it also demands a substantial degree of judgment and flexibility if it is to deal effectively with a variety of circumstances. Unfortunately, given its primary mission of regulating large reactors and given the public's insistence on stringent regulation of these reactors, the NRC may not be well suited for the job. Does this suggest, however, that all federal regulation of the medical uses of ionizing radiation should end? I think not. What is needed is

[6] To the extent that these other forms of ionizing radiation are regulated, it is through state regulation.

a more flexible regulatory approach such as that of the Food and Drug Administration (FDA).[7]

In making this point, I take strong issue with the portions of our report that refer to the NRC's overall regulatory approach as "burdensome, costly, and unduly prescriptive." Describing the NRC's approach in such an accusatory manner implies that the agency somehow has abused or mistreated those whom it regulates. To say the least, I have seen no such evidence nor do I believe that any exists. Demonizing an agency for adopting a regulatory approach that to many is quite reasonable serves no useful purpose. One needs to remember that the NRC has been accused of timidity as often, if not more so, as it has been charged with excessive zeal.

Propriety of the NRC's Quality Management and Misadministration Reporting Rules

The report takes sharp issue with two rules issued simultaneously in 1992 by the NRC. The first is the so-called quality management rule (10 CFR 35.32) and the second is the so-called misadministration reporting rule (10 CFR 35.33). To the committee's majority, these rules intrude excessively into the patient-physician relationship and represent a barrier to reasonable interaction between the NRC and its regulated community. Although I recognize the sincerity and intensity of my colleagues' views, I find neither rule substantively objectionable. First, the objections voiced by my colleagues essentially revisit points extensively debated within the NRC when it promulgated the two rules. As far as I can tell, the agency responded to the concerns raised in a reasonable and sensitive manner. In particular, it stressed that the rules did not mean that the agency approached misadministration issues in an absolutist or intrusive manner.[8] To the contrary, the NRC indicated that it had adopted an approach to "minimizing the occurrence of misadministrations"[9] and noted that the agency "realizes that it is impossible to prevent all mistakes. …"[10]

Second, despite my colleagues' objections to rules that affect the physician-patient relationship, I note that the NRC's Medical Policy Statement has never *barred* the agency from regulating the practice of medicine. Instead, it declares that the agency "will *minimize* intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of

[7] To say the least, numerous observers of the FDA would vigorously disagree with my assessment of the agency. Although the FDA, like other agencies, occasionally acts with excessive enthusiasm, I consider it to be highly sophisticated about the practice of medicine and to be generally flexible in dealing with medical practitioners.

[8] The NRC indicated that it promulgated the rules reluctantly in response to a doubling in the rate of reported misadministrations in the previous year. See 56 Fed. Reg. 34104 (July 25, 1991) at pp. 34109-10.

[9] Ibid. at p. 34110.

[10] Ibid.

medicine."[11] Clearly, the agency contemplated that some intrusion might be necessary from time to time to protect patients.

Third, with respect to the agency's quality management rule, I find little objectionable in its provisions. In essence, it simply directs licensees of the NRC to develop and maintain written quality management programs. Rather than tell any institution the precise program it must adopt, the rule, in one page, outlines a small number of general guidelines and asks licensees to submit copies of their written programs to the agency. I find it hard to imagine anyone objecting to the substantive guidelines set forth in the rule. They represent modest and minimal quality assurance approaches that any responsible licensee would undertake as far as I can tell. I stress this point because I remain convinced that what disturbs licensees is the way that the NRC has *enforced* the rule, not the rule per se. According to my colleagues, the agency has nitpicked the documents submitted by licensees in response to the quality management rule. That may or may not be, but the solution to this concern is to improve the NRC's review process, not to abolish the rule.

Fourth, with respect to the misadministration reporting rule, with one exception, I strongly disagree with my colleagues' objections to this rule. The NRC rule requires licensees to notify the agency when misadministrations occur and to explain how they occurred and what actions the licensee has taken to prevent recurrence. This rule is similar to rules at numerous agencies like the FDA, the Consumer Product Safety Commission, the Environmental Protection Agency, the National Highway Traffic Safety Administration, and others that require individuals and companies to share safety problems with bodies entrusted with the public's health.

With all due respect, I find the rule to be a reasonable, minimal intrusion into the practice of medicine. It is triggered only when a mistake has occurred and asks only that an explanation of the event be proffered. It is true that the rule requires reports of events that arguably present little meaningful risk to patients. This, in my view, is commendable and as it should be. As I have argued to my colleagues—obviously in a quite unsuccessful manner—health and safety agencies need to require reporting of marginal safety concerns to ensure that no events of consequence are missed.

The one valid point raised by the majority relates to notifying patients of misadministrations. Although it is a very close call, I agree that a rule that automatically requires notification of patients[12] probably produces more harm than benefit, especially with respect to trivial misadministrations. Given that a physician cannot generally undo a misadministration, it probably causes excessive anxiety in patients to be told that a minor misadministration occurred. Instead of

[11] This statement is reaffirmed in the agency's *Federal Register* notice promulgating the two rules. Ibid. at p. 34109.

[12] The only exception to the rule arises when, based on the physician's medical judgment, telling the patient would be harmful. See 10 CFR 35.33(a)(3).

this rule, I would be comfortable with a requirement that the physician or licensee indicate in its report to the NRC whether or not the patient was notified and explain the reasons for doing so or not doing so. The NRC should retain the authority to require patient notification in particularly serious misadministrations but should not insist on it in routine circumstances. One hopes that such a modification would stimulate a greater willingness among licensees to report misadministrations.

Finally, having found little *substantive* objection to the rules, as previously noted, I reach a different conclusion with respect to the NRC's *enforcement* of the rules. Again, I accept my colleagues' observation that the NRC's general enforcement philosophy, derived from regulating large reactors, may operate with excessive rigidity and formalism when it comes to the practice of medicine. I repeat my general support for transferring the medical use program to an agency like the FDA that is more experienced in dealing with the medical profession. I, however, disagree that the solution is simply to repeal all federal regulatory authority in this area.

RECOMMENDATIONS

The report's recommendations call for the abolition of the NRC's Medical Use Program. Instead of federal regulation, the report urges the establishment of a federal agency that would work with and coordinate efforts among the states and professional societies with respect to radiation safety. Among other things, such an agency would assist states in developing safety programs; investigate radiation accidents and issue reports about them; and help educate the public about the risks of radiation. As the committee put it, the agency would act as a "bully pulpit."[13]

I find aspects of this proposal appealing and sensible. I favor voluntary action when possible, I strongly support education efforts, and I endorse collaborative approaches between government and those whom it regulates. I even agree that it might make sense to transfer the NRC's authority to another agency. I part company, however, with respect to two aspects of the proposal.

Abolition of All Federal Regulatory Authority

I strongly disagree that the case has been made to repeal federal authority over the medical uses of ionizing radiation. Ionizing radiation, in my view, presents serious risks to the public health if not properly regulated. Without dwelling on the point, I am quite uncomfortable relying on state authorities and professional

[13] One new twist to the majority's proposal calls for the NRC to continue its regulatory authority to the extent that it would prohibit reactor-generated byproduct material from being shipped to any state that failed to establish a regulatory program over such material. This approach does not solve the problems that I see with the report. See footnote 15.

societies to safeguard the public health with respect to a technically challenging and potentially hazardous arena such as nuclear medicine. It is commendable for all concerned parties to work cooperatively if at all possible. However, one must take careful note of the following point: under the majority's approach, if and when the federal "bully pulpit" agency is confronted by the failure of a state regulatory system or state licensing authorities to address a crisis involving the medical use of ionizing radiation, the federal agency *will be without any power to act to protect the public*. So objectionable is federal authority to the committee members that they specifically eschew even a minuscule dollop of residual federal regulatory authority.[14] I find this unacceptable.[15] Regrettably, my experience with state authorities and professional medical societies does not leave me sanguine about their ability to deal with radiation hazards in a completely acceptable fashion. Not only do state authorities often have limited resources and expertise, they sometimes find it more difficult than would federal authorities to resist political pressure from those they regulate. The likely result of abandoning a federal regulatory presence is not a flowering of harmonious, effective relations among states, physicians, and hospitals. Rather, we are likely to see a patchwork quilt of approaches—some states will do an outstanding job of regulating, some will do an abysmal job, and others will likely approach regulation with a heavy hand that makes the NRC look benign by comparison. The essential difficulty with repealing NRC authority, in my judgment, is that at some point in the not-too-distant future, we will encounter a serious safety concern that is unaddressed, or incompetently addressed, that will result in unnecessary

[14] This is made clear in the committee's Recommendation B2, which calls for the repeal of the NRC's Medical Use Program in its entirety even if Congress fails to establish a "bully pulpit" federal presence. Despite language in committee Recommendation A1 stating that elimination of the NRC's Medical Use Program should take place only upon the creation of the federal "bully pulpit" program, Recommendation B2 demonstrates that the committee clearly intends the abolition of the Medical Use Program come what may.

[15] Again, I note the addition of language in the final version of the report indicating that the NRC might retain the authority to deny licenses to facilities in states that fail to establish programs to regulate reactor-generated byproduct materials. I see several problems with this approach. First, the proposal establishes no criteria for the NRC to apply in order to determine whether a state's regulatory program meets minimal safety needs. Without such criteria, states would be free to establish wholly inadequate regulatory schemes. Second, to the extent that the proposal might be amended to add criteria for NRC approval of state programs, this alternative would become, in effect, a watered-down "Agreement State" approach, requiring NRC monitoring of state regulatory programs—a far cry from the committee's stated goal of removing federal regulation of medical uses of ionizing radiation. Third, the proposal fails to indicate whether states would be obligated to upgrade their regulatory programs as technology changes or as new levels of risk are determined. Finally, the proposal provides no details regarding implementation. Whether or how the NRC would have such authority if all of the agency's Medical Use Program were abolished is unexplained.

deaths or illnesses. Should that occur, and I have little doubt that it will, the result might well be the reimposition of a federal regulatory system, but one that is more draconian and less effective than the one in place today.

Second, although I salute the conclusion in this report that the medical uses of ionizing radiation should be treated in uniform fashion, I object to the uniformity envisioned in the report, to wit, a repeal of all federal authority over its medical uses. Instead, I favor a reexamination of ionizing radiation risks as a whole and an appropriate restructuring of regulatory approaches. It may be that the regulation of reactor-generated byproducts can be minimized in a way that substantially reduces costs (and annoyance) without significantly increasing risks. If so, I favor such an approach. It may also be—and I strongly suspect it to be so—that we would find that other medical uses of ionizing radiation have been inadequately addressed under state regulation. I particularly worry about the widespread use of x-rays by medical technicians and marginal "medical" professionals such as chiropractors who may have little insight into the risks associated with these products. Let's consolidate the control of ionizing radiation but not simply end it.

CONCLUSION

I believe that the IOM report raises many important issues. As a number of my colleagues have noted, no one in the group agrees totally with all of the report's recommendations. In this spirit, I have tried to see the merits of the majority—and, indeed, there is merit in some of its views. In the end, however, I find that the case for abolishing federal regulatory authority over the medical use of ionizing radiation has not been made.

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