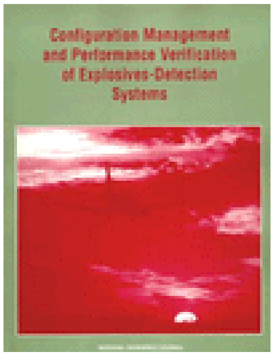


Configuration Management and Performance Verification of Explosives-Detection Systems

Panel on Technical Regulation of Explosives Detection Systems, Commission on Engineering and Technical Systems, National Research Council

ISBN: 0-309-59237-2, 88 pages, 8.5 x 11, (1998)

Configuration Management and Performance Verification of Explosives-Detection Systems

Panel on Technical Regulation of Explosives-Detection Systems
National Materials Advisory Board
Commission on Engineering and Technical Systems
National Research Council

Publication NMAB-482-3
NATIONAL ACADEMY PRESS
Washington, D.C. 1998

NATIONAL ACADEMY PRESS 2101 Constitution Avenue, N.W. Washington, DC 20418

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 competencies 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 National Academy of Sciences is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Bruce Alberts is president of the National Academy of Sciences.

The National Academy of Engineering was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. William Wulf is president of the National Academy of Engineering.

The Institute of Medicine was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility given to the National Academy of Sciences by its congressional charter to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education. Dr. Kenneth I. Shine is President of the Institute of Medicine.

The National Research Council was organized by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy's purposes of furthering knowledge and advising the federal government. Functioning in accordance with general policies determined by the Academy, the Council has become the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities. The Council is administered jointly by both Academies and the Institute of Medicine. Dr. Bruce Alberts and Dr. William Wulf are chairman and vice chairman, respectively, of the National Research Council.

The study by the National Materials Advisory Board was conducted under Contract No. DTFA03-94-C-00068 with the Federal Aviation Administration. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the organizations or agencies that provided support for the project.
Available in limited supply from:
National Materials Advisory Board
2101 Constitution Avenue, N.W.
HA-262
Washington, DC 20418
202-334-3505
nmab@nas.edu

Additional copies available for sale from: National Academy Press Box 285 2101 Constitution Ave., N.W. Washington, DC 20055
800-624-6242 202-334-3313 (in the Washington Metropolitan Area) http://www.nap.edu
International Standard Book Number: ISBN-0-309-0-6196-2

Printed in the United States of America.

PANEL ON TECHNICAL REGULATION OF EXPLOSIVES-DETECTION SYSTEMS

HARRY MARTZ (chair), Lawrence Livermore National Laboratory, Livermore, California
KATE ALVARADO, DNV Certification, Inc., Long Beach, California
JOHN BAER, International Management & Engineering Consultants, Annandale, Virginia
SUSAN DART, Dart Technology Strategies, Newport Beach, California
ROBERT GAGNE, Food and Drug Administration, Rockville, Maryland
DONALD LEBELL, Consultant, New York, New York
ARMIN PFOH, General Electric Research & Development, Niskayuna, New York
ANTHONY SHUMSKAS, BDM Engineering Services, Mclean, Virginia
MICHAEL STORY, Thermo Instrument Systems, Inc., San Jose, California

Technical Consultant

JOSEPH A. NAVARRO, JAN Associates, Inc., Bethesda, Maryland

National Materials Advisory Board Liaison

JAMES WAGNER, Case Western Reserve University, Cleveland, Ohio

National Materials Advisory Board Staff

SANDRA HYLAND, senior program manager
CHARLES T. HACH, staff officer
BONNIE SCARBOROUGH, staff officer
JANICE M. PRISCO, project assistant
ROBERT E. SCHAFRIK, director (until November 1997)
RICHARD CHAIT, director (after February 1998)

Government Liaisons

PAUL JANKOWSKI, Federal Aviation Administration Technical Center, Atlantic City, New Jersey
ALAN K. NOVAKOFF, Federal Aviation Administration Technical Center, Atlantic City, New Jersey
ARMEN A. SAHAGIAN, Federal Aviation Administration, Washington, D.C.

NATIONAL MATERIALS ADVISORY BOARD

Preface

The Federal Aviation Administration (FAA) of the U.S. Department of Transportation was established in 1958 to promote and ensure the safety of air travel. One objective of the FAA is to reduce the vulnerability of the civil air transport system to terrorist threats by employing procedural and technical means to detect and counter threats. The development of systems and devices to meet this objective was first authorized in the Air Transportation Security Act of 1974 (Public Law 93-366). The role of the FAA in aviation security was increased by the 1985 International Security and Development Cooperation Act (Public Law 99-83) that allowed for the expansion of the FAA' s research and development program.

The destruction of Pan American Airlines Flight 103 on December 21, 1988, over Lockerbie, Scotland, resulted in the creation of the President's Commission on Airline Security and Terrorism in 1989 and the incorporation of some of the recommendations of that commission into the Aviation Security Improvement Act of 1990 (Public Law 101-604). This act directs the FAA to develop technologies to detect explosives in checked baggage and, when these technologies are shown to meet FAA certification criteria, mandate the deployment of explosives-detection systems (EDSs)[1] in U.S. airports. In response to this directive, the FAA developed a set of certification criteria for automated bulk explosives-detection equipment, that is, systems that, without intervention by a human operator, detect explosives concealed in checked baggage. In 1994, the InVision CTX-5000 demonstrated in laboratory testing at the FAA William J. Hughes Technical Center (FAA Technical Center) that it was capable of performing at the specified level and was certified by the FAA as an EDS. The FAA desires a mechanism to ensure that subsequent copies of FAA certified EDSs meet certification criteria as they are produced and deployed and that they continue to meet these criteria over their lifetime in an operational environment.

The FAA requested that the National Research Council prepare a report assessing the configuration-management and performance-verification options for the development and regulation of commercially available EDSs and other systems designed for detection of explosives. The Panel on Technical Regulation of Explosives-Detection Systems was established by the National Materials Advisory Board of the National Research Council to (1) assess the advantages and disadvantages of methods used for configuration management and performance verification relative to the FAA' s needs for explosives-detection equipment regulation, (2) outline a "quality management program" that the FAA can follow that includes configuration management and performance verification and that will encourage commercial development and improvement of explosives-detection equipment while ensuring that such systems are manufactured to meet FAA certification requirements, and (3) outline a performance-verification strategy that the FAA can follow to ensure that EDSs continue to perform at certification specifications in the airport environment.

The Panel on Technical Regulation of Explosives-Detection Systems developed this report based on (1) panel meetings and technical literature provided to the panel by individual panel members, the FAA, and the National Research Council staff; and (2) presentations made by the FAA, manufacturers, and other experts who briefed the panel on existing FAA regulatory policies regarding security, bag-gage-screening technologies, quality systems and standards, and testing of explosives-detection equipment. Two members of the panel are also members of the National Research Council's Committee on Commercial Aviation Security, which oversaw this study, and provided the panel with committee findings that were relevant to the panel's task. In addition, the Chair of the Committee on Commercial Aviation

[1] The following terminology is used throughout this report. An *explosives-detection system* is a self-contained unit composed of one or more integrated devices that has passed the FAA's certification test. *Explosives-detection equipment* (also referred to as advanced technology) is any equipment, certified or otherwise, that can be used to detect explosives.

Security briefed the panel on committee findings and participated in one panel meeting.

The panel conducted five meetings between March 1996 and March 1997 to gather information used in developing this report. The panel also dedicated substantial time and effort to deliberating over their findings to develop, refine, and gain consensus on the conclusions and recommendations contained in this report.

Early in the study process, the panel recognized that the airport environment, like the social and political environment that surrounds it, is unlikely to remain static. Accordingly, the pace and magnitude of explosives-detection equipment deployments and the consequent priority of, and options for, regulating EDSs is scenario dependent. Thus, ideally, con-figuration-management and performance-verification strategies adopted by the FAA should be sufficiently robust and flexible to accommodate a range of scenarios as these scenarios shift over time.

HARRY MARTZ, CHAIR

PANEL ON TECHNICAL REGULATION OF

EXPLOSIVES-DETECTION SYSTEMS

Acknowledgments

The Panel on Technical Regulation of Explosives-Detection Systems would like to acknowledge the contributions of the individuals who contributed to this study, including the following speakers: Richard Beebe, Hewlett Packard; Admiral Cathal Flynn, Federal Aviation Administration; Keith Goll, Federal Aviation Administration; Matthew Hampton, General Accounting Office; Lok Koo, Federal Aviation Administration; Sarah Mowitt, Food and Drug Administration; Paul Polski, Federal Aviation Administration; Harvey Rudolph, Food and Drug Administration; Armen Sahagian, Federal Aviation Administration; Benno Stebler, Consultant; and James H. Williams, Federal Aviation Administration. The panel is also grateful for the contributions of the two contracting office technical representatives, Paul Jankowski and Alan K. Novakoff. In addition, the panel benefitted greatly from the technical insights of Lyle Malotky, Federal Aviation Administration, and Joseph A. Navarro, JAN Associates.

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making the published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their participation in the review of this report: H. John Denman, AlliedSignal Aerospace; Robert E. Green, Johns Hopkins University; A. Nadeem Ishaque, General Electric Company; Frank H. Laukien, Bruker Analytical Systems; Steven W. Percy, Vivid Technologies; Maxine L. Savitz, AlliedSignal; Howard Strait, Loral Federal Systems; Benno Stebler, consultant; and Steven Wolff, InVision Technologies.

While the individuals listed above have provided constructive comments and suggestions, it must be emphasized that responsibility for the final content of this report rests entirely with the authoring committee and the NRC.

For organizing panel meetings and directing this report to completion, the panel would like to thank Charles Hach, Sandra Hyland, Janice Prisco, and Bonnie Scarborough, staff members of the National Materials Advisory Board.

Contents

	Executive Summary	1
1	Introduction	13
	FAA Aviation Security Program	14
	Certified Explosives-Detection Systems	15
	Performance Verification of Aviation Security Equipment	16
	Report Organization	17
2	Stakeholder needs and Requirements	18
	FAA' s Needs	19
	Manufacturers' Needs	19
	Airport and Air Carrier Operators' Needs	19
	Alignment and Conflicts between Stakeholders' Needs	19
	Stakeholders' Needs in a Crisis Situation	20
3	Anatomy of Explosives-Detection Equipment	21
	Explosives-Detection Technologies	21
	Architecture of Explosives-Detection Equipment	21
	Role of Infrastructure on Explosives-Detection Equipment	23
4	Tools for Ensuring Operational Performance	24
	Configuration Management	24
	Performance Verification	27
	Quality Systems and Standards	29
5	Life-Cycle Management Plan	33
	Explosives-Detection Equipment Life Cycle	33
	Management Plan	33
	Configuration Management Plan	38
	Performance Verification	42
	Quality Systems and Standards	47
	Precertification Requirements	49
	References	51
	Appendices	
A	Explosives-Detection Technologies	55
B	Configuration Management Tools	59
C	Threat-Decision Paradigm	60
D	Alternative Quality Standards	61
E	Sample ISO 9000 Effort for a 50-Person Company	63
F	Test Protocol for Bulk Explosives-Detection Equipment	64
G	Biographical Sketches of Panel Members	67
	Glossary	69

Tables, Figures, and Boxes

Tables

ES-1 Seven Proposed Testing Levels during the Life Cycle of an EDS 7
ES-2 Types and Purposes of Test Objects 8
2-1 Current Role of the FAA for EDSs and for Noncertified Explosives-Detection Equipment 19
4-1 Seven Proposed Testing Levels during the Life Cycle of an EDS 27
5-1 Types and Purposes of Test Objects 43
5-2 Criteria for Classifying Problems with Explosives-Detection Equipment 49
A-1 Mass Density and Composition of Common Explosive Materials and Selected Nonthreat Items 56
A-2 Tabular Description of Each Operational Subsystem of a Conceptual EDS Based on Visible Light Transmission 58
A-3 Tabular Description of Each Critical Module of an EDS Based on X-Ray CT 58
B-1 Examples of Client-Server Configuration Management Tools 59

Figures

ES-1 Six phases in the life cycle of an EDS 4
ES-2 Configuration change process for an EDS during manufacture or operation 6
ES-3 Monitoring and verification testing for certification maintenance 9
ES-4 Responsibilities of stakeholders for moving from the engineering phase to certification 10
ES-5 Responsibilities of stakeholders for moving from certification to the manufacture of an EDS 11
ES-6 Responsibilities of stakeholders for moving from the manufacturing phase to the operational phase 11
3-1 Schematic block diagram of the operational subsystems comprising an explosives-detection system 22
4-1 Major divisions of configuration management 25
4-2 Graphical depiction of configuration control 26
4-3 Classes of configuration management tools 26
4-4 Factors contributing to the spread of the measured physical parameter(s) 29
4-5 ISO 9000 standards and guidelines 31
5-1 Five phases in the life cycle of an EDS 34
5-2 Activities over the life cycle of explosives-detection equipment 35
5-3 Responsibilities of stakeholders for moving from the engineering phase to certification 36

5-4 Responsibilities of stakeholders for moving from certification to the manufacture of an EDS 36
5-5 Responsibilities of stakeholders for moving from the manufacturing phase to the operational phase 37
5-6 Configuration change process for an EDS during manufacture or operation 40
5-7 Monitoring and verification testing for certification maintenance 45
5-8 Schematic representation of the relationship between various levels of performance verification test objects and the "real threat" and the relative practicality and degree of uncertainty associated with them 46
A-1 Hydrogen and nitrogen content of various explosive and nonexplosive materials 57
A-2 View of a conceptual EDS based on visible light transmission 57
A-3 Front view of an EDS based on x-ray CT 58
A-4 Side view of an EDS based on x-ray CT 58
C-1 Schematic drawing of the statistical decision theory paradigm 60
F-1 Example standard test article for daily performance verification of bulk explosives-detection equipment 65

Boxes

ES-1 Terminology for Explosives-Detection Equipment 2
ES-2 Certified Versus Noncertified Explosives-Detection Equipment 2
4-1 Attributes of an Effective Quality System 30
5-1 Best Manufacturing Practices Program of the Office of Naval Research 38

Acronyms

AAPM	American Association of Physicists in Medicine
CI	configuration item
CSCI	computer software configuration item
CT	computed tomography
EDS	explosives-detection system
FAA	Federal Aviation Administration
FDA	Food and Drag Administration
GMP	good manufacturing practices
ICAO	International Civil Aviation Organization
ISO	International Organization for Standardization
NRC	National Research Council
P_D	probability of detection
P_{FA}	probability of false alarm
SMPTE	Society of Motion Picture and Television Engineers
TWA	Trans World Airlines

Executive Summary

Terrorist incidents around the world involving commercial airplanes have received tremendous visibility, increasing the perception of vulnerability for those who fly, while recent bombing incidents in the United States have raised public awareness of the U.S.'s vulnerability to terrorism. Such events have sparked a vigorous debate about how to improve aviation security. Calls for improvements in the U.S. aviation security system have come from a wide variety of sources, ranging from local newspaper editors to the White House Commission on Aviation Safety and Security.[1] Critics and supporters alike have called for improvements in security personnel, such as increasing their numbers, improving training, and heightening public awareness of security threats, in addition, many have called for improvements in equipment for detecting weapons and explosives, including increasing the number of units deployed and developing new technologies.

The ability to detect weapons and explosives hidden in baggage is a critical element of aviation security. X-ray radiographic systems that screen checked and carry-on baggage for weapons and explosives have been in use for many years. Early systems focused on detecting weapons that might be used to hijack an airplane; more recently the focus has expanded to improving the ability of equipment to detect explosive devices in passenger bags. For more than a decade, the Federal Aviation Administration (FAA) has worked with manufacturers to improve the ability of x-ray radiographic systems to detect explosives and to develop new technologies for explosives detection. Several types of equipment, including machines that provide images of bag contents and instruments that sample the air around bags or the surfaces of bags for traces of explosive materials are commercially available but have only recently been widely deployed in the United States. Equipment that remotely senses a physical or chemical property of the object under investigation is termed *bulk*[2] explosives-detection equipment (see Box ES-1). Other types of equipment, called *trace* equipment, require that particles or vapor from the object under investigation be collected and identified. In 1996, the FAA was directed by the White House Commission on Aviation Safety and Security, under Public Law 104-264 (1996), to purchase and deploy this commercially available equipment to increase aviation security. At the same time, the FAA and manufacturers are continuing their efforts to develop explosives-detection equipment with improved capabilities.

To provide a quantitative assessment of the ability of explosives-detection equipment to detect a wide variety of explosives, the FAA has developed certification standards and a certification test protocol to measure performance of bulk explosives-detection equipment (FAA, 1993). These certification standards are based on classified FAA analyses of threats to aviation security and include parameters regarding the types and amounts of explosives to be detected, acceptable rates of detection and false alarms, and required baggage throughput rates.[3] The certification test protocol requires that, for each manufacturer's model, a single explosives-detection unit be tested at the FAA William J. Hughes Technical Center (FAA Technical Center) in Atlantic City, New Jersey, using a standard set of test bags. These bags are all similar in appearance and contents, but some contain explosives. Once a technology has passed the certification requirements, it is referred to as an explosives-detection system (EDS), as are all subsequent reproductions of the original unit (see Box ES-2).

With the certification of InVision' s CTX-5000 in 1994 it became important to know how the FAA can ensure that

[1] The White House Commission on Aviation Safety and Security was convened on July 25, 1996, just days after the explosion and crash of Trans World Airlines Flight 800. President Clinton requested an initial report from the commission specifically to address questions of aviation security (White House Commission on Aviation Safety and Security, 1996, 1997).

[2] In this report bulk explosives include all forms and configurations of an explosive at threat level (e.g., shaped, sheet, etc.).

[3] Specific certification criteria are classified.

reproductions of the originally tested unit are working properly at the manufacturing site before deployment and in the airport after deployment. Because each unit of a certified EDS is required to perform at certification level, the FAA must now develop a framework of procedures for manufacturers and operators that will ensure the required performance level of each unit. This framework must include performance requirements that can be measured at manufacturing sites and in airports and must specify the documentation and record-keeping that manufacturers and users must provide to maintain EDS certification.

BOX ES-1 TERMINOLOGY FOR EXPLOSIVES-DETECTION EQUIPMENT

In the field of explosives detection, an *explosives-detection system (EDS)* is a self-contained unit that has been certified by the FAA to detect, without operator intervention, the full range of explosives designated in the certification criteria. However, there is a wide variety of equipment that has not been demonstrated to perform at certification levels or for which there are no certification criteria.

In this report, the phrase EDS is used to describe certified equipment. The phrase *explosives-detection equipment* (also referred to as advanced technology) is used generically, describing any piece of equipment, certified or not, designed to detect explosives.

The FAA Aviation Security Program is embarking on a new phase in aviation security (i.e., ensuring the certification-level performance of individual EDS units after deployment, after maintenance, and after upgrades). As part of their role in maintaining aviation security, the FAA must be able to verify that EDSs are operating properly, which will involve defining performance requirements and establishing equipment testing protocols. At the same time, the FAA wants to encourage the continuing development of certified systems and devices, with the intent of improving performance and decreasing costs. Balancing the need to ensure the consistent performance of available equipment and the need to encourage the development of new and better equipment will be challenging. In a sense, the regulatory system the FAA puts in place now will influence the future of the explosives-detection field, which is still in its infancy. Because of the unknowable and changing nature of threats to aviation security, the regulatory system will also have to be flexible enough to adapt to changes in certification requirements and to allow rapid responses to emergencies by the FAA, EDS manufacturers, and equipment users.

The logistics of verifying EDS performance at manufacturing sites and in airports over the system's life cycle are complex. One well-known example of in-service detection performance verification is the standard used to test the metal-detecting portals commonly deployed in airports around the world (FAA, 1997a). These portals are tested by an individual carrying a weapon or simulated weapon through them. Analogously, one might reason that, to verify the detection performance of an EDS, an inspector could simply insert an appropriate explosive sample to ascertain if the machine gives the correct response. Although a few metal

BOX ES-2 CERTIFIED VERSUS NONCERTIFIED EXPLOSIVES-DETECTION EQUIPMENT

Public Law 101-604 (Aviation Security Improvement Act of 1990) states that "[n]o deployment or purchase of any explosive detection equipment . . . shall be required . . . unless the [FAA] Administrator certifies that, based on the results of tests conducted pursuant to protocols developed in consultation with expert scientists from outside the Federal Aviation Administration, such equipment alone or as part of an integrated system can detect under realistic air carrier operating conditions the amounts, configurations, and types of explosive material that would be likely to be used to cause catastrophic damage to commercial aircraft."

In response to this directive, the FAA developed certification criteria for explosives detection and test protocols that would determine if a unit of explosives-detection equipment meets those criteria. These certification criteria are classified and are linked to the FAA's ability to mandate implementation.

The Federal Aviation Reauthorization Act of 1996 (Public Law 104-246, 1996) directs the FAA to deploy (temporarily)both certified and noncertified systems. The FAA is purchasing and installing a variety of explosives detection equipment and is using the opportunity to improve installation and evaluation procedures. Although the FAA has no regulatory role in the design and manufacture of noncertified equipment, as purchaser the FAA may set performance standards and criteria against which to measure airport performance of this equipment. The air carriers may deploy explosives-detection systems, either FAA certified or noncertified, on their own without an FAA mandate.

guns (e.g., ferrous, nonferrous, nonmagnetic nonferrous) may effectively represent all guns in terms of verifying the detection performance of a metal-detection portal, a single— or even several—explosives can not represent the salient characteristics and properties of the many explosive types and arrangements that must be detected. Furthermore, because of the attendant safety problems, most airports and other public places forbid the handling of explosives. Therefore, developing effective testing procedures to ensure the proper operation of explosives-detection equipment, both when the equipment is manufactured and when it is in operation, will require creative solutions.

STUDY APPROACH AND SCOPE

In 1995, the FAA requested that the National Research Council (NRC) assist them in the development of a framework for ensuring proper detection performance by suggesting guidelines for the manufacture and deployment of EDSs. In response to this request, the NRC appointed the Panel on Technical Regulation of Explosives-Detection Systems, under the auspices of the Committee on Commercial Aviation Security of the National Materials Advisory Board. The panel was charged with assessing options for configuration management and performance verification for the development and regulation of FAA-certified commercial EDSs and other equipment designed to detect explosives. To accomplish these tasks, the panel took the following actions:

- assessed the advantages and disadvantages of various commercial approaches to configuration management and performance verification in terms of the FAA's regulation of explosives-detection equipment
- developed a framework for a performance-verification strategy that the FAA could use to ensure that EDSs perform at certification levels in airports
- outlined an overarching management plan that includes configuration management and performance verification to encourage commercial development and improvements in EDSs and to ensure that systems are manufactured, deployed, and maintained in such a way as to meet FAA certification requirements

Any framework for ensuring the certification-level performance of explosives-detection equipment must take into account the interests, capabilities, and needs of the various groups involved, including U.S. air carriers, who pay for and operate screening equipment; U.S. airports, which provide space and support to air carriers for aviation security; the FAA, which is responsible for maintaining aviation security; manufacturers of explosives-detection equipment, whose companies' reputations depend on their providing accurate and reliable equipment; the U.S. Congress, which appropriates funds for FAA development and deployment of explosives-detection equipment; and, most important, the flying public, who depend on the other groups to provide safe and secure air travel. The stakeholders most directly responsible for aviation security are the end users,[4] usually the air carriers, the FAA, and the equipment manufacturers. Because these stakeholders have both the responsibility for and the capability of ensuring aviation security, the recommendations in this report are directed toward them.

This Executive Summary is primarily focused on the role of the FAA in the certification of EDSs and the verification of performance levels of both new systems and systems in use in airports; less attention is paid to the roles of manufacturers and end users. A more in-depth discussion of manufacturers' and end users' roles can be found in the body of this report. Many of the practices and procedures recommended in this report are already included in FAA documents; the panel includes these recommendations to reinforce their importance and to place these issues in the overall framework of the manufacture, deployment, operation, and regulation of EDSs.

QUALITY SYSTEMS

For both hardware and software systems, a balance must be achieved between the predictive methodology of configuration management and the confirming methodology of performance verification. Configuration management, which encompasses change control and documentation, ensures that changes in manufacturing processes or materials and upgrades of equipment in service are assessed before they are implemented and that they are tracked to ensure that the configuration of units is known at all times. Performance verification comprises testing to ensure that system performance has not degraded unexpectedly as a result of the changes themselves, as a result of the synergistic effects of a number of small changes, or as a result of changes in performance over time. Typically, system managers use a *quality system* to balance performance verification and configuration management. The purpose of a quality system is to ensure consistent quality in design, development, production, installation, operation, maintenance, and upgrades of equipment.

Recommendation. Every stakeholder must have a quality system in place that includes oversight, validation, verification, and procedures for configuration management and performance verification covering that stakeholder's responsibilities throughout the life cycle of an EDS.

In the opinion of the panel, manufacturers without a quality system that incorporates configuration management will be unable to compete in competitive industries. Quality standards provide a framework for developing such effective quality systems. Perhaps the best-known and most widely used quality standard is the ISO 9000 series of quality sys

[4] Included with end users are the air carriers, airports, third-party equipment operators contracted by the air carrier or airport, and third-party maintenance providers contracted by the air carrier, airport, or equipment manufacturer.

tem standards, which allows individual companies or units within a company to develop a unique quality system that is effective for their organization (ISO, 1994). Numerous quality systems have been developed, each one tailored to the specific needs of the organization using it.

Recommendation. Because there is already a global movement toward using the ISO 9000 series of quality system standards, the panel recommends that the FAA base both its in-house quality system and its requirements for other quality systems on these standards. The FAA should accept the quality system of any stakeholder that has the following attributes:

- a definition of the critical parameters and their tolerances, procedures, and processes to be monitored
- documented evidence of an internal quality system
- a definition of the methods for controlling and verifying changes to procedures and processes
- a definition of an internal audit program
- provision for a third-party audit of conformance with the quality system

The panel concluded that if a stakeholder can demonstrate to the FAA—through a third-party audit—that its existing quality system has the salient attributes outlined above from the ISO 9000 series of quality standards, it should not be required to be formally certified as being compliant with a particular ISO 9000 standard.

QUALITY SYSTEMS AND LIFE-CYCLE PHASES

To determine the role of the FAA in the certification and deployment of EDSs, the panel found it convenient to identify five EDS life-cycle phases (see Figure ES-l):

- the *research phase*, which includes basic research and testing up to and including proof of concept and "breadboard" implementation of those concepts
- the *engineering phase*, which includes the development of the manufacturer's original design, modifications to that design, and leads to pilot production of a system for certification testing by the FAA
- the *manufacturing phase*, which includes pilot production, certification (performance and documentation of precertification testing and certification testing at the FAA Technical Center), and manufacturing (which includes the assembly and testing of reproductions of systems that have been certified and the incorporation of approved improvements and upgrades to the certified design)
- the *operational phase*, which includes initial deployment and normal use and operation
- the *retirement phase*, which includes the removal and disposal of a system

In its regulatory capacity, the FAA participates in two of these five phases: the manufacturing phase, through the change control process for design changes; and the operational phase, through the change control process for equipment maintenance or upgrades and verification testing for maintenance of certification (see Figure ES-1). Although the FAA has supported research on new concepts for explosives detection and the engineering of new explosives-detection technologies, in the regulatory arena, the FAA does not become officially involved until a manufacturer begins to prepare a unit for certification testing (FAA, 1993). The FAA tests the original explosives

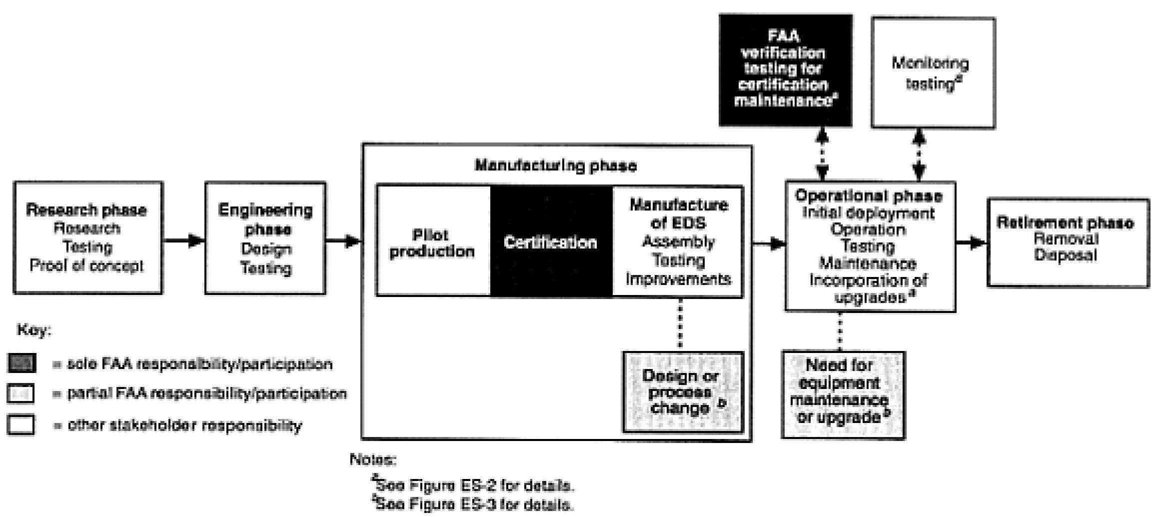


Figure ES-1
Five phases in the life cycle of an EDS.

detection equipment,[5] which is a product of the manufacturing phase; works with the manufacturer who produces the EDS units or incorporates improvements to the original design; and works with the end users who operate and maintain the EDS. The FAA may participate in development testing of engineering prototype systems leading to the first-run production system. On the other end of the life cycle, once an EDS has demonstrated that it can no longer perform at the levels required to maintain certification, the FAA may withdraw certification from that unit. The user is then responsible for the unit; they may choose to continue to use the uncertified unit in an application where certification is not required, or they may choose to retire the unit. Once certification is withdrawn, the FAA has no responsibilities for the retirement phase of the unit.

The panel focused on the three aspects of the EDS life cycle (certification, manufacturing, and operation) in which the FAA participates in a regulatory capacity. These three aspects can be thought of as encompassing the certification of an EDS and the maintenance of certification for duplicates of the certified system as well as for deployed EDSs. Most challenges to maintaining certification arise during the manufacturing and operation phases as a result of manufacturer or user requests to improve performance by incorporating design changes into currently manufactured systems and incorporating configuration changes into deployed systems. Another challenge is the EDS redesign required when a subsystem or specific technology that has been designed into the EDS becomes unavailable due to the rapid pace of technology changes or when a subcontractor of the EDS manufacturer discontinues a subsystem used in the EDS design. The overall impact of these changes or combinations of changes on performance may be poorly understood.

The panel endorses the requirement in the FAA certification criteria (FAA, 1993) specifying that quality systems should be in place prior to certification testing for each subsequent life-cycle phase of an EDS. Because each stakeholder has different responsibilities during each life-cycle phase, the quality systems may vary. But they must all have the attributes specified in the previous recommendation. Although individual stakeholder activities may already be under the control of quality systems, the panel believes that it is critically important to have comprehensive quality systems that cover all life-cycle phases of an EDS. Furthermore, it is important that each stakeholder periodically receive a third-party audit of their quality system, including, where applicable, a configuration audit.

Recommendation. Explosives-detection equipment presented to the FAA for certification testing must be the product of an implemented and documented manufacturing quality system. Subsequent units must be manufactured according to the same quality system to maintain certification.

Recommendation. The FAA should implement and document its own quality system under which precertification activities, certification testing, test standards development and maintenance, and testing for maintaining certification are conducted.

Recommendation. Each stakeholder must have a documented and auditable quality system that governs its specific responsibilities in the manufacture, deployment, operation, maintenance, and upgrading of EDSs.

Recommendation. The FAA should ensure that each stakeholder periodically receive an audit of their quality system— including (where applicable) a configuration audit—from an independent third-party auditor.

CHANGE CONTROL PROCESS

The change control process encompasses a proposal of a change to the design of explosives-detection equipment or to the configuration of an existing unit, agreement by all stakeholders on the change, implementation of the change, and verification of the impacts of the change. The keys to the successful implementation of a change control process, which must be included in an acceptable quality system, are the agreement of stakeholders on the classification of proposed changes; defined stakeholder involvement at each classification level; periodic audits of design and configuration changes and test results; and periodic testing of EDSs to determine that the combined effect of all design or configuration changes does not degrade EDS performance.

The panel found it useful to outline a change control process for EDSs in which changes in EDS designs or configurations are made in response to needs or problems identified by the manufacturer, the FAA, or the end user (see Figure Es-2). Changes to the design or configuration of an EDS may be desirable either during the manufacturing process or after the system has already been deployed. One critical aspect of making changes to an EDS is evaluating the potential impact of changes on the operation of the EDS in the context of each stakeholder's responsibilities. For example, users, who are responsible for installing and operating systems in the field, may be concerned about the effects of changes in throughput, floor plan area, weight, or costs. The FAA is likely to be concerned about the effects of a change on explosives-detection performance levels. Manufacturers may focus on compatibility with previously manufactured units. Every change must be ranked by each stakeholder for its potential impact on its area of concern.

Recommendation. All stakeholders (air carriers, FAA, equipment manufacturers) should agree prior to the manufacture or deployment of an EDS on a change classification system and process to ensure that stakeholders are notified of changes as necessary.

[5] The documentation of FAA certification outlines both precertification requirements and certification testing protocols for prospective EDSs.

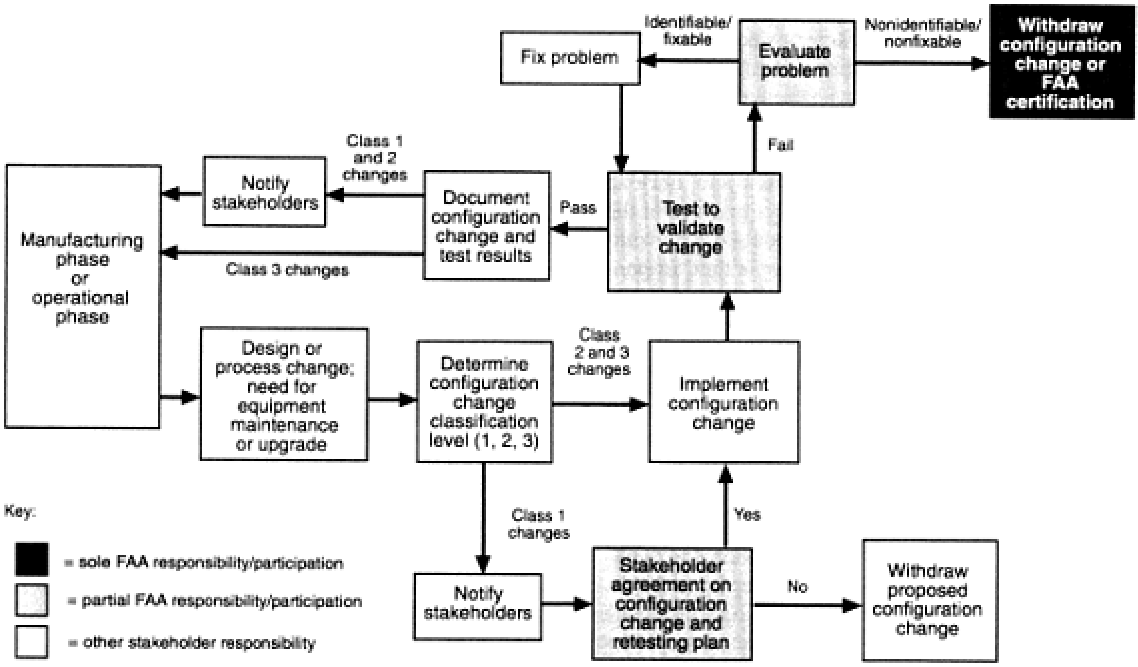


Figure ES-2
Configuration change process for an EDS during manufacture or operation.

The benefits of having a change classification process in place prior to the manufacture or deployment of an EDS include the incorporation of improvements with a minimum of confusion about the role of each stakeholder, the clarification of retesting required to confirm the effects of changes, and the empowerment of each stakeholder to evaluate EDS performance continually and suggest improvements. A typical change classification system ranks changes as follows:

- Class 1 changes are likely to affect system performance.
- Class 2 changes might affect some aspects of system performance.
- Class 3 changes are not likely to affect system performance.

Once a change classification process is in place, stakeholders who propose changes to an EDS design or to an individual EDS would have a clear approval process and implementation plan to follow. For example—if the three-tiered change classification process described above were adopted—once the classification level of a change has been determined, either the change would be implemented (Class 2 and Class 3) or the other stakeholders would be notified of the proposed change and arrangements would be made to obtain stakeholder agreement on the specific design or configuration change and retesting plan (Class 1). If no agreement can be reached, the stakeholders (i.e., FAA, manufacturers, and end users) can modify the change or retesting plan or can withdraw the proposed change from consideration. The FAA, however, would act as the final arbiter in such a situation. Once a design or configuration change has been made, the EDS would be tested according to the specified retesting plan and the test results documented for future audits (see Figure ES-2). Although, in reality, determining the class of a change will be the responsibility of the manufacturer, review of the classification of changes (and the appropriateness of such classifications) should be included in a third-party configuration audit.

Recommendation. Configuration-control boards such as the ones used in many industries should be established to determine which proposed changes will be implemented and the implementation and testing conditions that will be imposed.

All proposed changes would be brought before a board that has the expertise and authority to determine their potential impact and determine the appropriate change classification level. The panel envisions the establishment of several configuration-control boards, each responsible for overseeing one or more aspects of the EDS life cycle. For example, the manufacturers might establish a configuration-control board that includes representatives of their research, engineering, quality assurance, marketing, and service areas. Users, such as air carders, could establish a board that includes representation from operations, security, and other departments to oversee upgrades and the maintenance of EDSs in airports. The FAA should establish a configuration-control board with representation from all stakeholders to oversee Class 1 changes. The FAA should have final authority in resolving the debate on whether or not a Class 1 change should be approved or require recertification testing.

FAA TESTING FOR MAINTENANCE OF CERTIFICATION

The panel found it useful to define seven levels of testing that might take place during the life cycle of an EDS: precertification, certification, baseline, qualification, verification, monitoring, and self-diagnosis (see Table ES-1). Although other types of testing may be undertaken by the FAA, manufacturers, or end users, the seven types listed above are the ones related to certification and maintenance of certification. The FAA's current certification documentation specifies the testing protocols and test objects to be used for precertification and certification testing (FAA, 1993). Testing protocols and test objects are being developed for the four test levels that follow manufacturing and deployment— qualification, verification, monitoring, and self-diagnosis.

The panel focused its discussions of performance testing on postcertification testing, which the panel recommends be required for maintaining certification. The panel defined the purpose of each postcertification testing level as follows (see Table ES-l):

- *Qualification testing* determines if a new unit meets its performance requirements. Qualification testing would be performed at the manufacturing site—prior to shipping—to assure the purchaser that the individual unit has been properly manufactured.
- *Verification testing* determines if a deployed unit meets its performance requirements. Verification testing would normally be performed in the airport at initial deployment and at specified intervals using a secondary standard bag set to demonstrate to the user and the FAA that the unit is functioning as specified.
- *Monitoring* critical system parameters determines if unit performance has changed. System parameters for a computed-tomography (CT)-based system such as the CTX-5000 might include spatial resolution and contrast sensitivity. Monitoring would normally be done in the airport at specified intervals using test articles to demonstrate to the user and the FAA that unit performance has not changed.
- *Self-diagnosis* determines if components or subsystems of a unit are functional. Ideally, self-diagnostics will evolve to the point in which they are capable of determining if components and subsystems are operating according to their individual specifications. Self-diagnosis includes the continuous measurement of subsystem parameters (e.g., voltages and currents) during routine operation as well as self-diagnostic routines on machine start-up.

The development of appropriate test objects and testing protocols will be critical to each level of testing. The panel has identified three types of test objects that should be required for each type of EDS: a primary standard bag set, a secondary standard bag set, and individual test articles to test critical system parameters (see Table ES-2).

Recommendation. The FAA should require a wide variety of tests for maintaining EDS certification, including qualification testing and periodic verification testing of detection performance levels (using a secondary standard bag set), frequent monitoring of critical system parameters (using test articles), and continuous self-diagnosis of subsystem parameters (e.g., voltages and currents) to detect incipient problems.

Note that validation of critical and subsystem parameter ranges may require monitoring the correlation of these ranges with equipment performance over time—even after deployment. In this context, system performance pertains to the ability of the equipment to detect the explosive compositions

TABLE ES-1 Seven Proposed Testing Levels during the Life Cycle of an EDS

Test Level	Purpose	Location	Test Objects	Frequency
Precertification	Determine if technology is ready for certification testing.	Manufacturer's site	Test articles	Once[a]
Certification of an EDS	Determine if technology performance is at certification level.	FAA Technical Center	Primary standard bag set	Once[a]
or Baseline	Establish baseline performance for noncertified equipment.	FAA Technical Center	Primary standard bag set	Once[a]
Qualification	Verify the performance of an individual manufactured unit to qualify that unit for deployment.	Manufacturer's site	Secondary standard bag set and test articles	Once[a]
Verification	Verify the performance of an individual deployed unit to confirm that performance is at qualification level.	Airport	Secondary standard bag set	At specified occasional intervals
Monitoring	Verify critical system parameters to confirm the consistency of system performance.	Airport	Test articles	At specified frequent intervals
Self-diagnosis	Verify that subsystem parameters are operating according to specifications for continuous "system health."	Airport	None	Continuous

[a]May require retesting until the unit passes the specified test.

and configurations (e.g., sheet and nonsheet bulk explosives) defined by the FAA's certification criteria. Therefore, parameter values measured outside of accepted ranges should trigger testing the equipment with the secondary standard bag set in the field.

TABLE ES-2 Types and Purposes of Test Objects

Test Objects	Definition	Purpose
Primary standard bag set	Representative passenger bags, some containing explosives at threat quantity	Simulate threat
Secondary standard bag set	Representative passenger bags, some containing simulants representing explosives at threat quantity	Simulate primary standard bag set (requires no special safety-related handling permits or precautions)
Test articles	Individual articles, including items such as simulants, the InVision IQ simulants test bag, and ASTM (1993) standardized step wedges and CT phantoms	Elicit a predetermined response to test critical system parameters

DEVELOPMENT OF TEST OBJECTS

The FAA has already developed a standard bag set that includes bags with explosives for certification testing (FAA, 1993). In this report this bag set is referred to as the primary standard bag set. Because EDSs in airports or at manufacturers' sites cannot easily be tested with real explosives, the FAA must develop a secondary standard bag set consisting of representative passenger bags, some containing standard materials that simulate explosive threat materials and some without any simulated threats. The secondary standard bag set could be used periodically to test the detection performance of EDSs in airports or at manufacturers' sites. However, in order for such tests to be relevant to measuring the certified performance of an EDS, the secondary standard bag set must be validated against the primary standard bag set, perhaps at the time of certification testing. Figure ES-3 illustrates a verification testing process.

The critical issues for tests using the secondary standard bag set are determining the performance levels that will be acceptable to the FAA and determining how those performance levels will be measured. All of the major stakeholders—the FAA, the manufacturers, and the users—should be involved in the development of secondary standards and test protocols for testing in nonsecure areas, such as manufacturers' sites, or public places, such as airports. However, because the FAA regularly gathers intelligence on threats to civil aviation security and is responsible for ensuring aviation security, only the FAA can determine acceptable performance levels. Of course, the FAA must be mindful of the practical limitations of testing and the capabilities of EDSs. For example, requiring that certification performance levels be used as performance requirements in an airport would be counterproductive because testing several hundred bags would disrupt airport operations, and testing with explosives in a public environment could be unsafe.

Recommendation. For qualification and verification testing, the FAA should work with EDS manufacturers and users to develop a secondary standard bag set for each specific technology or technology class.

Recommendation. The secondary standard bag set should be controlled to assure reliable test results, as is done by the FAA for the primary standard bag set. It is important that the FAA periodically (on the order of the lifetime of the simulants) verify the condition, configuration, and performance of the secondary standard bag set.

Recommendation. For monitoring the performance of EDSs, the FAA should work with manufacturers to develop a set of critical system parameters (and their tolerances) that could be monitored frequently and recorded to track changes in performance during normal operations or to verify performance after maintenance or upgrading.

Recommendation. The panel recommends that the FAA verify critical system parameters during certification testing.

Monitoring critical system parameters will require test articles and practical test protocols, as well as specified nominal values and ranges for each critical system parameter. For CT-based systems, such as InVision's CTX-5000,[6] critical system parameters might include spatial resolution and contrast sensitivity. The manufacturer, who is the most familiar with a specific technology, is best qualified to establish critical system parameters and their tolerances, which the FAA could verify during certification testing. Figure ES-3 illustrates the process of monitoring testing for an EDS in the operational phase.

The stakeholders must agree on the process that will be followed if an EDS unit fails during monitoring, verification, or qualification testing, and on criteria for withdrawing an individual EDS unit from operation. In addition, a process should be in place for the FAA and the manufacturer to identify the failure mode, correct it, and requalify the EDS unit for use. The FAA and the manufacturer should determine if this particular failure mode is common to a particular

[6] The CTX-5000 was the first FAA-certified EDS. The InVision CTX-5000-SP has also been certified.

version of an EDS and whether they need to go through the same correction and requalifying procedure. If the cause of the failure camnot be determined or corrected, the EDS unit or units should be withdrawn from service indefinitely. Furthermore, if several units of a particular version fail and the cause of failure cannot be determined or corrected, certification should be withdrawn for that version.

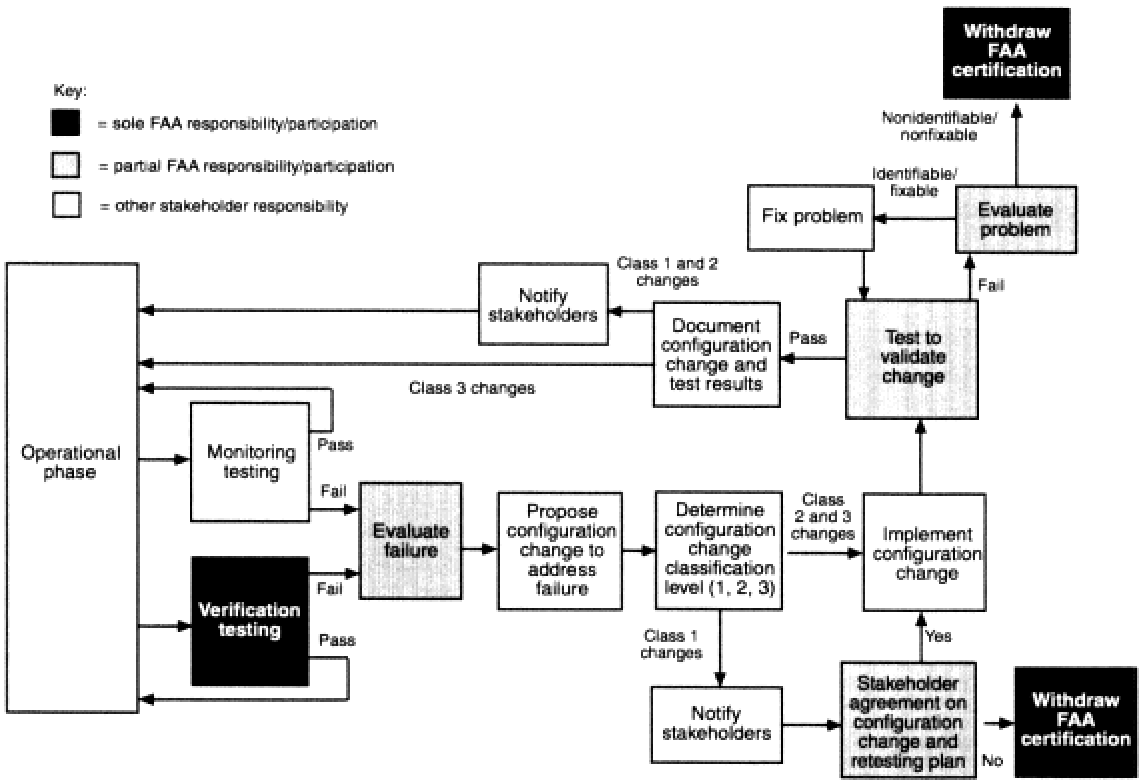


Figure ES-3
Monitoring and verification testing for certification maintenance.

Because the monitoring testing would use standard test articles, it would be useful to include the monitoring test as a part of the qualification testing for newly manufactured EDSs prior to shipping them to airports. In other words, the qualification testing protocol should include protocol for validation of the test article to be used for monitoring.

The manufacturer's design will include many subsystem parameters that could be measured by frequent periodic diagnostic tests, if not continuous self-diagnostic tests as the system operates. Changes in voltages and currents, for example, can be early warnings of a change in performance characteristics. The manufacturer should establish acceptable ranges as part of the quality system and should document the measurements.

NONCERTIFIED EXPLOSIVES-DETECTION EQUIPMENT

The previous discussion was focused on certification and certification maintenance for EDSs. However, the FAA also purchases noncertified equipment for airport demonstrations and operational testing. As purchaser, the FAA should require that the manufacturers of noncertified equipment have in place a quality system that meets the same standards as the quality systems for manufacturers of certified equipment. However, to verify the performance of noncertified equipment, the FAA must establish a "baseline performance" level for each explosives-detection equipment design. The panel has labeled testing to determine the baseline performance of noncertified equipment "baseline testing" (see Table ES-1).

Certification testing could be used to establish the baseline performance for some types of explosives-detection equipment that does not meet all of the certification criteria (e.g., advanced radiography). The baseline performance would be the "score" that the equipment achieved on the certification test.

However, the FAA also must establish a testing protocol to determine the baseline performance for equipment for which certification criteria have not been developed (e.g., trace detection equipment). For trace technologies, which are designed to collect and identify traces of explosives on the outside surfaces of bags or in the surrounding air, the FAA has already developed a baseline test that the panel believes may provide a basis for determining baseline performance (FAA, 1997b).

Recommendation. The FAA should require that the manufacturers of noncertified equipment demonstrate the same level of quality system covering both manufacturing and upgrade as required for manufacturers of EDSs when noncertified equipment is purchased by the FAA for airport demonstrations, operational testing, or airport deployment.

Recommendation. The FAA should ensure that the manufacturers of noncertified explosives-detection equipment purchased by the FAA periodically receive an audit of their quality system—including a configuration audit—from an independent third-party auditor.

Recommendation. The FAA should ensure that airlines, other end users, and organizations responsible for maintenance and upgrades (e.g., manufacturers or third-party service providers) demonstrate a quality system that covers the operation, maintenance, and upgrade of noncertified EDSs that are purchased by the FAA for airport demonstrations, operational testing, or airport deployment. Such a quality system should meet the FAA's requirements of quality systems used by operators and maintainers of certified explosives-detection equipment.

SUMMARY

The FAA plays the leading role in establishing the performance requirements for operational EDSs, just as it has for laboratory performance requirements for certification. Performance requirements include not only the acceptable detection and false-alarm rates, but also the testing protocols and the test objects used to determine system performance. Like other stakeholders in the manufacture and deployment of EDSs, the FAA must also have a quality system in place that defines the critical parameters and their tolerances, procedures, and processes to be monitored; documents the implementation of the quality system; defines procedures for controlling and verifying changes to procedures and processes; and provides for third-party audits of conformance.

The FAA's main role prior to certification testing is to develop certification test objects and test protocols and to demonstrate that they are under the control of an acceptable quality system (see Figure ES-4). The FAA must establish standards for performance of certified systems and develop and validate a secondary standard bag set and other test objects for testing at the manufacturer's site and in airports (see Figures ES-5 and ES-6). These performance standards can be the same as the ones used for qualification testing at the manufacturer's facilities and can use the same secondary standard bag set to demonstrate the consistency of performance at the factory and in the airport. Once an EDS is deployed, the FAA is responsible for periodic verification testing to ensure consistent performance over the life of the EDS. Another postdeployment issue is the maintenance of explosives-detection equipment. In many industries, including the aircraft/airline industries, a third-party service provider is contracted by the user (e.g., the airlines) for maintenance of the equipment. There is no reason to believe that this will not occur, at some point, with explosives-detection equipment. Third-party audits of manufacturers, users, third-party service providers, and the FAA will ensure compliance with all configuration-management and performance-verification requirements.

FAA	Manufacturer	User
Develop primary standard bag set.	Identify system baseline configuration.	Participate in and facilitate precertification airport testing for explosives-detection technology.
Demonstrate that a quality system is used for all certification test objects and test protocols.	Identify critical system parameters, including acceptable values and ranges.	
Ensure that a quality system is in place for the manufacturing and operational life cycle phases of an EDS.	Demonstrate a quality system for manufacturing, including a change control process.	
Develop secondary standard bag set.	Demonstrate completion of precertification activities.	

Figure ES-4
Responsibilities of stakeholders for moving from the engineering phase to certification.

FAA	Manufacturer	User
Ensure the development of a secondary standard bag set.	Develop proposed manufacturing change classification levels and procedures and facilitate acceptance by other stakeholders.	Participate in the development of manufacturing change classification levels and procedures.
Validate secondary standard bag set.		
Participate in the development of manufacturing change classification levels and procedures.	Participate in the development of performance standards, test protocols, and test objects for qualification testing.	Participate in the development of performance standards, test protocols, and test objects for qualification testing.
Establish performance standards and test protocols for qualification testing.		
Validate test objects for qualification testing.		

Figure ES-5
Responsibilities of stakeholders for moving from certification to the manufacture of an EDS

FAA	Manufacturer	User
Establish performance standards and test protocols for validation and monitoring testing.	Participate in the development of operational configuration change process.	Demonstrate quality systems for EDS testing, maintenance, and upgrades.
Validate test objects for validation and monitoring testing.	Participate in the development of performance standards, test protocols, and test objects for verification and monitoring testing.	Develop an operational configuration change process.
Participate in the development of operational configuration change process.	Notify FAA and users of maintenance requirements and opportunities for upgrades.	Participate in the development of performance standards, test protocols, and test objects for verification and monitoring testing.
Perform periodic verification testing and maintain data.	Maintain self-diagnostics data.	Perform routine maintenance.
Perform qualification testing with manufacturer.	Maintain configuration documentation of units to be deployed.	Perform monitoring testing and maintain data.
		Maintain configuration documentation of units in airports.

Figure ES-6
Responsibilities of stakeholders for moving from the manufacturing phase to the operational phase.

REFERENCES

ASTM (American Society for Testing and Materials). 1993. F792-88. Design and Use of Ionizing Radiation Equipment for the Detection of Items Prohibited in Controlled Access Areas. West Conshohocken, Pa.: American Society for Testing and Materials.

FAA (Federal Aviation Administration). 1993. Management Plan for Explosives Detection System Certification Testing. Washington, D.C.: Federal Aviation Administration.

FAA. 1997a. Metal Detector Calibration/Certification Procedures for Course #00032. Washington, D.C.: Federal Aviation Administration.

FAA. 1997b. Summary of Trace Testing Methodology in Support of the Security Equipment Integrated Product Team. Washington, D.C.: Federal Aviation Administration.

ISO (International Organization for Standardization). 1994. ISO 9001, Quality Systems: Model for Quality Assurance in Design, Development, Production, Installation, and Servicing, 2nd ed. Geneva, Switzerland: International Organization for Standardization.

White House Commission on Aviation Safety and Security. 1996. Initial Report to the President, September 9, Washington, D.C. Available on the internet: http://www.aviationcommission.dot.gov

White House Commission on Aviation Safety and Security. 1997. Final Report to the President, February 12, Washington, D.C. Available on the internet: http://www.aviationcommission.dot.gov

1

Introduction

The mission of the Federal Aviation Administration (FAA) is to promote and ensure the safety and security of air travel in the United States. The FAA has fostered an air travel system that is safer than virtually any other means of travel on Earth (White House Commission on Aviation Safety and Security, 1996, 1997) and, in partnership with several administrations, has continually improved aviation safety and security by recognizing new and potential threats and implementing policies to counter them.

The years since the mid-1960s have seen the implementation of many new approaches to improving aviation security. In the late 1960s, increased hijackings resulted in the establishment of the Anti-Hijacking Program of the FAA through the Air Transportation Security Act of 1974 (Public Law 93-366). This program spurred the implementation in U.S. airports of the now-familiar metal-detection screening portals for passengers and the x-ray inspection systems for carry-on baggage. The destruction of Pan American Airlines Flight 103 over Lockerbie, Scotland, on December 21, 1988, resulted in the creation of a Commission on Airline Security and Terrorism in 1989 by President Bush (President's Commission on Aviation Security and Terrorism, 1990), which led to his signing of the Aviation Security Improvement Act of 1990 (Public Law 101-604). Most recently, the White House Commission on Aviation Safety and Security published a report specifically addressing aviation security (White House Commission on Aviation Safety and Security, 1997). These events, along with other terrorist incidents in the United States and throughout the world and the perceived vulnerability and visibility of commercial airplanes as the targets of such terrorism, have sparked vigorous debate on how to improve aviation security. From the White House Commission on Aviation Safety and Security to the local newspapers, calls for more and better-trained security personnel, increased security awareness, and an improvement in the overall aviation security system are resulting in a focus on the detection of weapons and explosives.

One aspect of an overall aviation security system is technology for screening passenger baggage to determine if the bags contain anything that could be a threat to an airplane, from weapons that could be used in a hijacking to explosives intended to cause the airplane to explode in midair. The FAA has responded to the American public's desire for more-effective aviation security by fielding an unprecedented variety and number of new technologies for detecting explosives in checked passenger bags. These new technologies can peer through a bag to provide an image that can be used to determine the bag's contents or sample the air around a bag or even the surface of the bag itself to determine if traces of explosive materials are present and to indicate the need for more-extensive scrutiny of that bag. Many of the technologies being fielded today were developed within the past ten years, and more are under development through the efforts of manufacturers and the FAA.

Now that the FAA, along with many foreign governments and airports, is fielding this wide variety of technologies to detect explosives, one question has come to the forefront: How can the FAA, the manufacturer, and the end user determine when the equipment is working properly at the manufacturing site before deployment or in the airport after deployment? The metal-detecting portals common in airports around the world can be tested by walking through the portal carrying a weapon or simulated weapon and determining whether the machine gives the correct response. Analogously, to determine if a machine to detect explosives is working, an inspector could test the machine with a sample of an appropriate explosive to determine if the correct response is given. However, because of the attendant safety problems, most airports and other public places forbid the handling of explosives. Therefore, the testing of systems and devices to detect explosives will require more-creative solutions to provide assurance of proper operation to all of the stakeholders, including the air carriers, who pay for and operate screening equipment; the airports, who provide space and support to the air carriers for aviation security; the FAA, whose mission is to ensure aviation security; the equipment manufacturers, who establish their companies' reputations by providing accurate and reliable equipment; and the flying public, who depend on the other parties to work together to ensure safe and secure air travel operations. The stakeholders most directly responsible for aviation security are the end users,[1] usually the air carriers, the FAA, and the equipment manufacturers. Because these stakeholders have both the responsibility for and the capability of ensuring aviation security, the recommendations in this report are directed toward them.

Intuitively it is not unreasonable to suspect that detecting threats to aviation security is a straightforward process and that a primary standard threat object (e.g., an explosive) could easily be defined. If such were the case, a nonexplosive secondary standard related to the primary standard could be produced and used to test the performance of explosives-detection equipment[2] in an airport. The nature of the threat to aviation security, however, is not singularly defined. There are, in fact, several explosive compounds, which can be formulated into many different explosives and configured into an infinite number of shapes. Adding to this complexity is the fact that there are a medley of benign materials and objects contained in passenger baggage that could be misinterpreted as an explosive threat. These complications make it impracticable to establish a single meter bar for evaluating the performance of explosives-detection equipment.

The manufacturers and users of explosives-detection equipment are not alone in their need to ensure that a difficult-to-test, complicated mix of hardware, firmware, and software works correctly. Manufacturers and users of fighter airplanes, medical computed tomography (CT) x-ray systems, and even the international telecommunications system face similar dilemmas every day. There is no one solution that can ensure that these systems will continually operate properly. In practice, manufacturers and users of any system rely on a mix of testing and of controlling the quality and makeup of the system's components and subsystems to gain sufficient confidence in proper system performance.

For both hardware and software systems, configuration management, which encompasses change control and documentation, provides assurance that the impacts of any changes in manufacturing processes or materials are assessed before the changes are implemented and that any changes made are tracked so that performance can be maintained into the future. The other side of the coin is performance verification—testing to ensure that system performance has not degraded due to unanticipated causes or due to the synergistic effects of a series of small changes, each of which alone would not be expected to have an impact on system performance. Typically, system managers utilize a *quality system*[3] to balance the ability of configuration management to control changes to and maintain the configuration of a system (with known satisfactory performance) with performance verification, which provides a direct measure of system performance.

FAA AVIATION SECURITY PROGRAM

The FAA Aviation Security Program, by regulating the deployment of systems and other equipment to detect explosives, is embarking on a new phase in ensuring aviation security. The FAA's role in this mix of configuration management and performance verification is complicated. In its role in ensuring aviation security, it must be able to verify that explosives-detection equipment are operating properly. The FAA, however, also wants to encourage the development of competing systems and devices, with the intent of improving operational performance while decreasing costs. Achieving a balance between the need to ensure consistent performance of available equipment and the need for equipment with improved performance will be challenging. In a sense, the regulatory system that the FAA mandates now will influence the future of the field of explosives detection, which is currently in its infancy.

The concepts of configuration management and performance verification are not new to the FAA as a regulatory agency. The FAA regularly applies these principles in certifying aircraft and associated components through the FAA' s Type Certification process (FAA, 1996). However, the changing and unpredictable nature of the threat against aviation security makes the challenge of regulating explosives-detection equipment unique, because today's most sophisticated explosives-detection technologies may in fact be obsolescent as a result of tomorrow's explosive threats. In comparison, the product lifetime of other complicated systems, such as cellular telephones or personal computers, is determined predominantly by (comparatively) less threatening market forces. Furthermore, FAA-regulated aviation equipment such as aircraft must operate safely and effectively every day, and therefore they receive the necessary attention and scrutiny to ensure that they do so. The visibility (and often times the implementation) of aviation security equipment and procedures, however, is crisis dependent.

[1] Included with end users are the air carriers, airports, third-party equipment operators contracted by the air carrier or airport, and third-party maintenance providers contracted by the air carrier, airport, or equipment manufacturer.

[2] The following terminology is used throughout this report. An *explosives-detection system* is a self-contained unit composed of one or more integrated devices that has passed the FAA's certification test. *Explosives-detection equipment* is any equipment, certified or otherwise, that can be used to detect explosives.

[3] A *quality system* is a model for quality assurance in design, development, production, and maintenance. In addition, it defines and documents a stakeholder's configuration-management and performance-verification procedures. A *quality standard* specifies the requirements of the quality system (ISO, 1994). Finally, the *quality* of a product is the degree to which it satisfies the wants or needs of a specific customer, or may be stated in terms of the degree to which it conforms to specification (Blanchard, 1986).

Months, or even years, of low-threat situations can be quickly interrupted by times of high-level threats, as in the failed 1995 plot of Ramzi Ahmed Yousef to place bombs on U.S. commercial jetliners. During the periods of relative tranquillity, the FAA should develop and implement a system to enable immediate response and quick deployment of explosives-detection equipment in times of crisis. Furthermore, the FAA must maintain procedures for handling certification, deployment, and maintenance of explosives-detection equipment in times of stability and in times of crisis.

An automated explosives-detection system (EDS) consists of hardware, software, and firmware that determines the presence of an explosive device in baggage without operator intervention. To make up a fully operational aviation security system, a human operator is needed as well to perform the functions required for alarm resolution. The panel believes that a means to test and to continually improve the performance of the human operator is imperative. Although a competent human operator is required for an effective security system, this study focuses on the configuration management and performance verification of the hardware, firmware, and software.

In developing a regulatory framework for explosives-detection equipment, the FAA requested that the National Research Council provide guidance on the FAA's role in the manufacture and deployment of explosives-detection equipment, especially with regard to the regulation of certified EDSs. The National Research Council appointed a panel — the Panel on Technical Regulation of Explosives-Detection Systems, under the supervision of the Committee on Commercial Aviation Security—to assess configuration-management and performance-verification options for the development and regulation of EDSs and other equipment designed for detection of explosives. To accomplish these tasks, the panel

- assessed the advantages and disadvantages, relative to the FAA's needs for explosives-detection equipment regulation, of various commercial approaches for configuration management and performance verification
- developed a framework for a performance-verification strategy that the FAA could implement to ensure that FAA-certified EDSs continue to perform at certification standards in the airport environment
- outlined an overarching management plan, inclusive of configuration management and performance verification, that will encourage commercial development and improvement of EDSs while ensuring that such systems are manufactured, deployed, operated, and maintained to meet FAA certification requirements

CERTIFIED EXPLOSIVES-DETECTION SYSTEMS

The primary objective of aviation security is to prevent explosives and other threat objects from being brought aboard commercial aircraft. The Aviation Security Improvement Act of 1990 (Public Law 101-604) directs the FAA to develop technologies to detect explosives in checked baggage and, when technologies are shown to meet the criteria of the Act by passing FAA certification testing, mandate the deployment of certified systems in U.S. airports. In response to this directive, the FAA developed a set of certification criteria[4] for automated bulk[5] detection systems, that is, systems that detect bulk explosives[6] without intervention by a human operator (FAA, 1993). These certification criteria specify the types and amounts of explosives that must be detected, the detection and false-alarm rates that would be acceptable, and a throughput rate that is compatible with air carrier operation. Certification testing of candidate detection systems takes place at the FAA William J. Hughes Technical Center (FAA Technical Center) in Atlantic City, New Jersey, and equipment that is demonstrated to meet the certification criteria is designated as an EDS.

In 1994, the InVision CTX-5000 (and later the CTX-5000-SP and CTX-5500) was certified by the FAA as an EDS. These two machines are the only FAA-certified EDSs at the time of this report. Simulated passenger baggage,[7] with a percentage of the bags containing explosives, is inspected to determine detection rates, false-alarm rates, and throughput of a candidate detection system. The use of explosive material is the truest test for determining whether a system is capable of detecting a particular explosive. It is unrealistic, however, to subject subsequently manufactured copies of an EDS to the extensive testing performed at the FAA Technical Center. Because it is illegal to bring explosives into most U.S. airports, it is unlikely that explosive materials will be used in airports regularly to verify performance of an EDS. However, the FAA, the traveling public, the air carriers (who pay to purchase, deploy, and operate passenger and baggage

[4] Public Law 101-604 states that "[n]o deployment or purchase of any explosive detection equipment . . . shall be required . . . unless the [FAA] Administrator certifies that, based on the results of tests conducted pursuant to protocols developed in consultation with expert scientists from outside the Federal Aviation Administration, such equipment alone or as part of an integrated system can detect under realistic air carrier operating conditions the amounts, configurations, and types of explosive material that would be likely to be used to cause catastrophic damage to commercial aircraft." These certification criteria are classified and are linked to the FAA's ability to mandate implementation. The air carriers may deploy EDSs, either FAA certified or noncertified, on their own without an FAA mandate. Note that the Federal Aviation Reauthorization Act of 1996 (Public Law 104-264) directs the Administrator to deploy (temporarily) both certified and noncertified systems.

[5] Equipment that remotely senses a physical or chemical property of the object under investigation is termed *bulk* explosives-detection equipment. Other types of equipment, called *trace* equipment, require that particles or vapor from the object under investigation be collected and identified. More detail is provided in Appendix A.

[6] In this report bulk explosives include all forms and configurations of an explosive at threat level (e.g., shaped, sheet, etc.).

[7] The explosives-detection equipment is tested with a *primary standard bag set*, which consists of "typical" passenger bags, some of which contain explosives at threat quantities.

screening equipment), and the manufacturers need to be assured that subsequently manufactured units, at the time of deployment and throughout their service life, meet the same performance requirements (e.g., detection rates, false-alarm rates, and throughput rates) as the unit that passed certification testing.

PERFORMANCE VERIFICATION OF AVIATION SECURITY EQUIPMENT

As a result of the recommendations of the White House Commission on Aviation Safety and Security, the FAA was directed to deploy commercially available (certified and noncertified) explosives-detection equipment that will significantly enhance aviation security (Public Law 104-264). Therefore, the FAA needs a means to verify the performance of certified and noncertified explosives-detection equipment in the field. To verify performance, a baseline level of performance must be established from which to reference the results of a field test. For example, for certification testing of explosives-detection equipment, the FAA has established a set of bags (the primary standard bag set) held at the FAA Technical Center, which is intended to be representative of the general population of international passenger bags (FAA, 1993). This test bag set consists of two subsets: (1) a threat subset, which contains explosives and is used to measure equipment detection performance, and (2) a nonthreat subset, which does not contain explosives and is used to measure the false-alarm rate of the equipment. The certification test is, in essence, an operational test that represents the only performance baseline available to the FAA.

Similarly, the FAA has developed a baseline test that is used to determine the baseline performance of noncertified bulk explosives-detection equipment to be deployed in airports. The FAA tests such equipment against the same categories and amounts of explosives that are used in certification testing. Determination of which equipment is deployed (by the FAA) is related to the average probability of detection (for each device) over the given categories of explosives, and is also related to the false-alarm rate.

Unlike bulk detection devices, there are no defined FAA certification criterion for trace detection devices. Trace detection devices axe based on direct chemical identification of either particles of explosive material or vapors given off by explosive material. These devices require three distinct steps to be effective: (1) sample collection, (2) transfer of a sample to a chemical detector, and (3) sample analysis. Sample collection and transfer are accomplished by using a high-volume air flow to gather vapors or dislodge particles from surfaces or by making physical contact with the subject (e.g., identification with a wipe). Sample analysis techniques employ a variety of detection methods, including gas chromatography, chemical luminescence, and mass spectroscopy (NRC, 1993, 1996). Trace detection techniques are capable of detecting the presence of explosive materials but are unable to determine if they are present in threat quantities. Therefore, it is impossible to establish a test protocol for trace detection devices that is based on identifying the presence of a threat amount of explosives. An FAA approval process has, however, been established to determine which trace detection devices of the FAA will deploy (FAA, 1997a). A variation of the test protocol used in the FAA approval process may be applicable to maintaining a baseline level of performance in devices for detecting trace amounts of explosives.

The FAA's protocol for evaluating trace explosives-detection equipment uses extremely small amounts (of known quantity) of each category of explosives on a variety of substrates, with some substrates intentionally left uncontaminated. Several trace explosives-detection devices were shown by the FAA to be capable of finding explosive materials on the surface of various types of carry-on luggage. These devices are currently being deployed.

To be assured that certified and noncertified deployed equipment continue to meet FAA baseline performance specifications (without transporting the entire FAA primary standard bag set to every airport or every EDS off the production line to the FAA Technical Center for testing), a protocol must be developed to verify the performance of such systems, both at the manufacturing site and in the airport environment.

The FAA has already established a test protocol to verify performance at manufacturing sites and airports for certain types of security equipment. For example, the FAA regularly tests passenger-screening portals using a standard set of guns, determining if the metal-detection portal alarm sounds for each test gun, as it is designed to do. This FAA test is performed immediately after manufacture, after a metal-detection portal is installed, whenever a metal-detection portal is moved, and periodically to "spot check" the security system. In addition, air carriers regularly conduct their own tests to check the operation of their security equipment (FAA, 1997b).

The x-ray radiographic equipment that is currently used for screening carry-on baggage requires an operator to view a transmission x-ray image of each bag and scrutinize the contents of the bag for items that may be a threat to aviation security.[8] To test this equipment, the manufacturer, the FAA, and the air carriers periodically use a standard test object, such as the step wedge (with wires) to measure spacial resolution and contrast sensitivity as described in ASTM F792-88 (1993), to determine baseline performance. Implicit in this test is the assumption that the results of the test correlate with the ability of the equipment to present clear, high spatial resolution and high contrast sensitivity images of the

[8] Current legal interpretation allows the air carriers to search only for items that are a threat to the aircraft or air crew. They may not conduct a search to determine if a person is carrying other illegal but nonthreat items such as drugs (NRC, 1996).

contents of the bag so that equipment operators recognize threat objects in hand-carried items.

As described in ASTM F792-88 (1993), the test step wedge is not meant to simulate a weapon or explosive device, nor does it consist of explosive material. The step wedge is used, rather, to test the sensitivity and dynamic range of the x-ray imaging equipment. The adequacy of the operation of the equipment, as determined by this test, is then used as an *indirect* measure of its efficacy in imaging threat objects. This is an example of the use of secondary standards in airport testing of security equipment. Because explosives are not allowed in airports and a site license is required for manufacturers to handle them, secondary standards and associated test protocols for performance verification of explosives-detection equipment are needed.

REPORT ORGANIZATION

This report discusses an integrated life-cycle management plan for explosives-detection equipment that will aid the FAA in ensuring the production quality and operational consistency of EDSs, as well as the acceptable performance of recently deployed noncertified explosives-detection equipment. In addition, recommendations are made regarding performance verification of deployed noncertified explosives-detection equipment. Stakeholder (FAA, manufacturers, air carriers, and airports) needs and requirements of the FAA's management plan are discussed briefly in Chapter 2. Chapter 3 introduces the anatomy of explosives-detection equipment to put into context the recommendations regarding configuration management and performance verification made in the report. Chapter 4 outlines available configuration-management and performance-verification options and reviews several quality standards for use in developing a quality system. Finally, in Chapter 5 the panel's recommendations for a management plan are made, and the associated roles and responsibilities of the stakeholders in maintaining the performance of certified and noncertified explosives-detection equipment are discussed.

2

Stakeholder Needs and Requirements

There are many groups interested in ensuring aviation security, including manufacturers of explosives-detection equipment, the FAA, airports, air carriers, the public, and Congress. Those most directly involved in effecting aviation security, however, are the equipment manufacturers, the FAA, and the users, usually the air carriers. It is these select stakeholders together who have both the capability and the responsibility to ensure aviation security and, therefore, to whom the panel directs the recommendations contained in this report. Regardless of the balance of financial responsibility between airports, air carriers, and the government for aviation security, all are stakeholders in that all have certain expectations of and a need for operating and managing explosives-detection equipment over its life cycle.

The stakeholders' actions over the life cycle of the explosives-detection equipment are shaped by the needs of the stakeholders in aviation security and are affected by new detection technologies, changing threats, and economic uncertainties. Therefore, the evolution of explosives-detection equipment is dependent on actions taken by or for the stakeholders as a result of external developments. The expertise and capabilities of the individual stakeholders dictate the delegation of responsibility for such actions.

In its role of ensuring aviation security, the FAA must define the threat to aviation security and performance requirements for explosives-detection equipment while ensuring that the manufacturers of these systems continue to produce high-quality equipment. Furthermore, the FAA is responsible for ensuring that explosives-detection equipment, which likely will be maintained by the users, operates properly. Involving all the stakeholders in developing the FAA's management plan would allow each stakeholder to incorporate its different needs into the plan, while utilizing individual capabilities to achieve the common goal of improving aviation security.

The stakeholders need a management plan that encompasses manufacturing, certification, deployment, maintenance, and operational performance of explosives-detection equipment. That is, not only must the management plan ensure that as-manufactured explosives-detection equipment meets the same FAA requirements that the original, certified equipment met, but also that each unit must continue to meet the FAA's performance requirements over the time they are operating in airports. Therefore, the process outlined in this report can be thought of as encompassing certification and maintenance of certification over the life cycle of an explosives-detection system (EDS).

For noncertified explosives-detection equipment, as is being purchased by the FAA for deployment pursuant to the Federal Aviation Reauthorization Act of 1996 (Public Law 104-264), the role of the FAA is not as clear. Although the FAA will establish some baseline performance[1] for each type of equipment it deploys in airports, it does not have a regulatory role specifying a predetermined level of performance of noncertified equipment, as it does for EDS. However, as the customer who purchases explosives-detection equipment and deploys it in airports, the FAA should hold deployed, noncertified explosives-detection equipment to its baseline detection performance. Table 2-1 outlines several key differences in the role of the FAA for EDSs and for noncertified explosives-detection equipment.[2]

In this chapter, the panel outlines the needs of the stakeholders and how the needs of each stakeholder align or conflict with the needs of other stakeholders with respect to the life-cycle management plan for explosives-detection equipment. Discussion focuses on the FAA's interaction with the other stakeholders regarding certified EDSs and includes the FAA's role in the purchase, deployment, and regulation of noncertified equipment as appropriate.

[1] Baseline performance is discussed in more depth in Chapter 4.

[2] Table 2-1 indicates the current role of the FAA and does not reflect the panel's recommendations for the future. The panel's recommendations in Chapter 5 include that baseline performance of noncertified explosives-detection equipment be established and maintained.

TABLE 2-1 Current Role of the FAA for EDSs and for Noncertified Explosives-Detection Equipment

FAA Action	EDS	Noncertified Explosives-Detection Equipment
Mandate deployment by air carriers	yes	no
Establish minimum performance requirements	yes	no
Purchase and deploy in airports[a]	yes	yes

[a] Note that, even in the absence of a mandate, air carriers and other users can purchase and deploy certified and noncertified explosives-detection equipment in airports.

FAA'S NEEDS

For all stakeholders, the most important aspect of the FAA's management plan is that it ensures that explosives-detection equipment, as manufactured and used in airports, will meet FAA performance specifications. For the FAA, an additional concern is that the management plan and any associated quality standard, configuration-management tool, or performance-verification protocol associated with it must also be credible. That is, all stakeholders, including the general public, must be confident that the FAA's management plan is effective in ensuring that explosives-detection equipment is operating properly. A management plan that does not have the confidence of the stakeholders is unlikely to be deployed effectively and may not be successful in maintaining the baseline performance of explosives-detection equipment.

The management plan must also be flexible enough to handle changes in FAA certification standards. As the field of explosives-detection technology matures, and as threat types change, the FAA may need to modify their certification criteria to reflect changes in types (i.e., composition), amounts, or configurations of explosives that require detection. The FAA certification criteria may also need to be modified to become more representative of the performance required in airports. The implications of these changes for equipment being manufactured and for explosives-detection equipment already in the field are not clear. For clarity, the FAA should specify what impact future changes in their certification criteria will have on the manufacture and operation of equipment certified under current certification criteria.

MANUFACTURERS' NEEDS

For successful implementation of explosives-detection equipment into the aviation system, the FAA's management plan must incorporate the manufacturers' specific needs. An ideal management plan would ensure both consistent manufacturing quality, resulting in an EDS that detects explosives as required, and effective incorporation of improvements in design and manufacturing, resulting in lower costs and better performance.

On the assumption that the FAA's management plan will require manufacturers to have a quality system in place, the manufacturers would need a quality system that is easy to implement and that is cost effective for their operations. Manufacturers and potential buyers and users of explosives-detection equipment (both international and domestic) recognize the credibility associated with FAA certification. Explosives-detection equipment manufacturers, therefore, would benefit if the quality system and standard associated with FAA certification were also internationally recognized as credible.

AIRPORT AND AIR CARRIER OPERATORS' NEEDS

Traditionally, air carriers have been held financially responsible for aviation security.[3] Air carriers are required to provide metal-detector portals, x-ray radiographic screening equipment for checked and carry-on baggage, and security personnel at passenger security checkpoints. The airports are responsible for providing a place for security checkpoints and for maintaining general airport security.

As with the needs of the manufacturers, successful implementation of explosives-detection equipment into the aviation system requires that the FAA's management plan incorporate the specific needs of the users. From the users' perspective, an ideal management plan would ensure consistent detection performance as well as seamless integration of the task of explosives detection into the users' baggage-handling systems at minimal cost.

From the standpoint of the air carriers, therefore, the FAA's management plan should ensure that explosives-detection equipment is consistently effective and reliable. At the same time, the FAA should ensure that the manufacturers provide guidelines and procedures for maintenance, repair, and upgrade such that deployed equipment maintains suitable detection performance levels in the field. The FAA and the end users should review these guidelines and procedures with the manufacturers until concurrence is attained between the FAA, the manufacturers, and the end users. With clear guidelines and procedures, the users could plan their maintenance schedules and expenditures as they do now for standard baggage-handling equipment.

ALIGNMENT AND CONFLICTS BETWEEN STAKEHOLDERS' NEEDS

The FAA's needs reflect those of the other stakeholders in that they desire a management plan that perpetuates air travel that is safe and secure, which is the ultimate goal of

[3] Note that the Federal Reauthorization Act of 1996 (Public Law 104-264) directs the Administrator of the FAA to deploy (including purchase) commercially available explosives-detection equipment. This is a significant change from previous policy.

the FAA-air carrier-manufacturer partnership. However, the FAA's need to regulate the equipment and deployment scenarios may on occasion conflict with the business goals of the air carriers and manufacturers.

The FAA, along with the equipment manufacturers, desires a management plan that fosters the development of a market for explosives-detection equipment that provides for continual improvement in cost and performance. However, regulation may conflict with the need to continually make changes and improvements to equipment. The FAA's ultimate goal of widespread deployment of explosives-detection equipment may conflict with the air carriers need for uninterrupted flow in their baggage-handling operations and their desire to keep operational costs at a minimum.

Conflicts are inevitable between regulators and those they regulate. With an appropriate management plan, however, the FAA may be able to identify these conflicts early and resolve them with input from all stakeholders. It will also facilitate changes believed to be desirable by the FAA.

STAKEHOLDERS' NEEDS IN A CRISIS SITUATION

There are situations in which the operation of airport security equipment can be expected to be closely examined, which include

- specific threats against a particular flight (e.g., a bomb threat)
- a period of general high threat level (e.g., the FAA concludes that the probability of a terrorist incident is much higher than normal and consequently additional safeguards are activated to protect the public)
- an aircraft incident such as an in-flight explosion that could be attributed to a terrorist bomb

In the first two cases, it is reasonable to assume that the security-screening equipment will be relied on to provide a significant portion of the defense against the threat. In the last case, there will surely be an inquiry to determine if the explosives-detection equipment that serviced the flight were operating properly, and it may lead to a period of high threat levels until the cause of the incident is understood. In all three cases it may be beneficial to archive data collected by automated EDSs for a limited period of time (e.g., until the flights for which data are collected land safely) before it is permanently destroyed.

These crisis situations, in which the need to protect the traveling public will be paramount, demand that the capabilities of explosives-detection equipment be well understood and verifiable. This might be achieved through the adoption of a management plan for the equipment that includes the following aspects:

- tracks all changes made to the equipment and the effect they had on its performance
- establishes procedures that verify the performance of the equipment

A management plan that takes advantage of individual stakeholder needs and capabilities, and specifies the proper delineation of the role of each stakeholder, is a step toward an effective deployment of both certified and noncertified explosives-detection equipment.

3

Anatomy of Explosives-Detection Equipment

The objective of explosives-detection equipment is to detect certain types and amounts of explosive material with a high detection rate, a low false-alarm rate, and a throughput rate that makes it practical to be used in commercial airports. An explosive is a chemical compound that reacts rapidly, generating substantial amounts of heat and pressure. Most chemical explosives are organic compounds or mixtures consisting principally of hydrogen, carbon, nitrogen, and oxygen. Plastic explosives are of particular concern due to physical properties that make them easy to conceal and difficult to detect.

EXPLOSIVES-DETECTION TECHNOLOGIES

Bulk explosives-detection techniques remotely sense some physical or chemical property of an object under investigation to determine if it is an explosive. Such techniques often exploit the high nitrogen and oxygen content found in explosives. The relative amounts of hydrogen, nitrogen, oxygen, and other elements (e.g., carbon) can be used to discriminate explosive from nonexplosive materials. However, for each density window in which there is a cluster of explosive materials, some nonexplosives, such as plastics, clothing, and narcotics, may also be included (see Table A-1 and Figure A-1 in Appendix A). It is therefore the comparison of a number of relative amounts, or windows in a multidimensional space, that will discriminate explosive materials more specifically.

In some bulk explosives-detection techniques, the measurement of material density is limited and is therefore not sufficient to distinguish explosives from nonexplosives. In these cases, the use of geometric information such as size, shape, and volume of material with a certain density are utilized to decrease the degree of ambiguity and increase the accuracy of the system. The ability to detect the physical appearance (pattern recognition) of certain materials or objects (e.g., wires and detonators) can also be used to overcome shortcomings in separating the chemical components of the substance in question from those of surrounding non-threat items.

Trace explosives-detection equipment is based on the physical transport of vapor or particulates of explosives from the object under investigation to a unit for direct chemical identification. In contrast to bulk explosives detection, which can identify both the type and the approximate amount of explosive present, trace explosives detection can only indicate the presence of explosive material and, in some cases, the type of explosive. The strength of the detection signal for trace detection equipment is not related to the quantity of explosives present.

Trace detection techniques are less likely than bulk detection techniques to misidentify common, nonthreat items as explosive materials, but they suffer from missed detections due to inadequate sample collection.

Descriptions of the broad categories of explosives-detection technologies are given in Appendix A, with more comprehensive discussion of the wide variety of explosives-detection technologies to be found in other references (NRC, 1993, 1996; OTA, 1991, 1992). In the following sections, bulk explosives-detection equipment is considered to be the archetype explosives-detection equipment. Where significant differences exist between the bulk approach and the trace approach, trace detection technologies are discussed separately.

ARCHITECTURE OF EXPLOSIVES-DETECTION EQUIPMENT

Explosives-detection equipment can be delineated into operational subsystems (Figure 3-1), each of which performs a function crucial to overall system performance and, as such, is important for configuration management and performance verification. In addition, the explosives-detection equipment infrastructure consists of support utilities, power supplies, transport mechanisms, baggage-handling interfaces, communications network, and a physical structure to house the equipment. There are likely a wide variety of approaches to selecting operational subsystems, from one manufacturer to another and, perhaps, between different models manufactured by one manufacturer. Therefore, the manufacturers of explosives-detection equipment are best suited to determine how the operational subsystems are identified. The following is one example of how the equipment could be broken down into four operational subsystems:

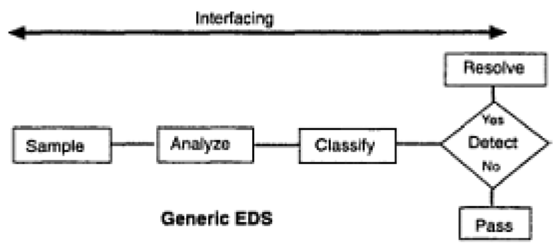


Figure 3-1 Schematic block diagram of the operational subsystems comprising an explosives-detection system.

- Sampling—collecting information about the bag that is necessary to characterize it. A detector is used to obtain the responses from threat and nonthreat objects.
- Analyzing—converting the sampled information into an interpretable form, such as a visible image, a total mass spectrum, shape, density, effective atomic number or other output, as an input to the classifying operational subsystem.
- Classifying—using the properties of the object and its constituents, as determined by the analyzing operational subsystem to classify the sample as a threat or nonthreat object.
- Interfacing—displaying key detection information and system condition information to an operator, technician, or automated security system.

Detection is the process of combining all information from the operational subsystems and making a decision (by a computer) as to whether or not an alarm should be activated for subsequent resolution by other explosives-detection equipment or a human operator. Each of the operational subsystems relies on one or more software, firmware, or hardware components.

As discussed in later chapters, delineating a unit of explosives-detection equipment into operational subsystems, such as the four discussed above, with associated hardware, firmware, and software components enables effective performance verification and configuration management and may foster equipment development, maintenance, and upgrades. The details of which system components are assigned to which operational subsystems, however, should be left to the manufacturers' discretion. The operational subsystems, in some cases, differ between trace detection and bulk detection techniques, as discussed below.

Sampling

The purpose of sampling is to obtain chemical or physical information from baggage. The critical components needed for sampling include a detector and sometimes an illuminator. For example, x-ray computed tomography (CT) relies on x-ray radiation to illuminate and elicit a response from explosive materials that differs from that obtained from nonthreat materials. In this case, the illuminator is an x-ray tube that deposits energy into the baggage under observation, and the detector is an x-ray detector that collects and analyzes x-rays after they have interacted with the baggage. The interactions of x-rays with the baggage are then used to measure the different physical parameters associated with individual objects within the baggage. Another technology for bulk explosives detection involves the use of nuclear particles (e.g., neutrons) to illuminate the sample.

Vapor and particle detection techniques use a collector to gather the vapor and particulates of the explosive from an object under observation. Sample collection is accomplished by using high-volume air flow to gather vapors or dislodge particles from surfaces or by wiping the surface.

Analysis

During analysis, information that is acquired during sampling is related to a measurable parameter associated with the objects within the baggage. The analysis subsystem consists of the entire data-acquisition, processing, and analysis system to transform raw data to physical parameter(s). It includes data processing in preparation for signal detection and presentation to threat-decision functions and algorithms. The analysis subsystem relies on a substantial mix of hardware, software, and firmware components. For example, an x-ray CT EDS utilizes x-ray detectors, electronic preamplifiers and amplifiers, digital filtering and image reconstruction algorithms, and signal and image processing algorithms to analyze the contents of baggage. For these CT systems, the measured parameters include the x-ray attenuation coefficient averaged over the x-ray energy spectrum, which is a function of the physical density and average atomic number of the material, shape, and location of the objects within the baggage under observation.

Techniques for trace detection sample analysis employ a variety of chemical methods, including gas chromatography, chemical luminescence, and ion mobility spectroscopy. These methods can determine chemical properties such as molecular weight, absorptivity, retention time, fluorescent emission, and electron affinity of the vapor or particulate matter collected to distinguish the sample from nonexplosive materials (NRC, 1993, 1996).

Classification

The purpose of classification is to determine the existence of a threat through the use of data analysis and manipulation algorithms applied during analysis. During classification, objects within the baggage are identified and classified, and their attributes are compared with those of threat objects. Although the classifier subsystem may include hardware, software, and firmware components, software components typically dominate this subsystem. Notification of the presence of a threat can be in the form of data input to the next stage of a multistage EDS or the presentation of information on the threat to the computer or human operator of an explosives-detection device.

For a trace detection system, only the existence of a chemical or set of chemicals can be discerned. No shape, volume, or weight information can be ascertained.

Interfacing

Even in the most automated explosives-detection equipment available at the time of this report (including the FAA-certified CTX-5000-SP EDS), human operators are necessary for detection and alarm resolution and therefore must interface with the EDS for proper operation. The user interface comprises those components of the equipment that provide audible and visible indication of the operational status of the equipment. These indicators include not only those associated with normal operation of the explosives-detection equipment but, more importantly, those involved with the presentation of information (typically in the form of visual images) concerning the possibility of a threat within the baggage under observation.

ROLE OF INFRASTRUCTURE ON EXPLOSIVES-DETECTION EQUIPMENT

Although infrastructure is not defined in this report as an operational subsystem, it is critical in enabling the proper operation of explosives-detection equipment. Infrastructure includes the basic, underlying mechanical and electrical framework of the equipment. The infrastructure comprises those elements of the explosives-detection equipment that provide the mechanical structure, the interconnection of different electrical and mechanical components, the mechanical transport of the baggage under observation, and the overall control and coordination of the different equipment functions, the interface between different devices in a multiple-device system, and the airport or air carrier bag-gage-handling system.

To elucidate the architecture of explosives-detection equipment, two examples with a complete tabular description of each equipment module are provided in Appendix A. The first example represents a conceptual picture of an explosives-detection device whereas the second is based on currently used technologies.

4

Tools for Ensuring Operational Performance

To ensure operational performance throughout the life cycle of a unit of explosives-detection equipment, the FAA should implement a life-cycle management plan that defines and documents configuration-management, performance-verification, and quality-assurance procedures for all stakeholders. This chapter describes "tools" that could be used by the stakeholders to produce explosives-detection equipment that consistently meets the performance requirements of the FAA.

Individually, none of the tools will ensure the operational performance of explosives-detection equipment—neither configuration management nor performance verification are singularly effective methods of ensuring the performance of explosives-detection equipment. These tools must be integrated synergistically with a quality system to effectively maintain equipment performance at a level acceptable to the FAA.

CONFIGURATION MANAGEMENT

Configuration management is a process to identify the functional and physical characteristics of a software, firmware, or hardware *item* during its life cycle; control changes to those characteristics; and record and report change processing and implementation status. Configuration management is applied to ensure operational efficiency and control cost and may be applied to achieve uniformity in procedures and practices within the FAA and between the FAA and industry. Properly applied, configuration management could provide the FAA and manufacturers of explosives-detection equipment with the formal mechanisms for determining how changes affect operating characteristics, including detection ability. Applying configuration-management techniques, however, requires judgment to be exercised: Inconsistent, unmoderated configuration management may compromise performance; rigid, inflexible configuration management may stifle innovation. Thus, effective configuration management relies on the knowledge and judgment of the people responsible for implementing the configuration-management plan.

Configuration management is performed by subjecting every change to a configuration item (CI) to review and approval by authorized and knowledgeable personnel. A CI is a collection of hardware, software, and firmware that is a uniquely identifiable subset of the system and that represents the smallest portion of the system to be subject to configuration-control procedures (DOD, 1995; Buckley, 1993).[1] Furthermore, documentation that describes the configuration of a CI is itself a configuration item that needs to be defined and maintained. CIs that are specific to system software are referred to as computer software configuration items[2] (DOD, 1995). CIs must be individually controlled, because any change to a CI may affect the performance of the explosives-detection equipment. It is crucial that all explosives-detection equipment have a readily auditable list of CIs that includes their current status.

Configuration management, as shown in Figure 4-1, consists of four basic functions[3] (DOD, 1995; Buckley, 1993; Blanchard, 1986):

- *Configuration identification*: identification of the functional and physical characteristics of a software, firmware, or hardware CI at any given time during its life cycle. This includes formal selection of CIs and

---

[1] Any one of the operational subsystems (e.g., analyzer) can be identified as a CI. Conversely, another operational subsystem (e.g., sampling) might consist of several CIs (e.g., x-ray source, x-ray detector, power supply). The designation of a CI is often a judgment call made by a project manager or project management team. It is immaterial to configuration management how this decision is made (Buckley, 1993).

[2] For the purpose of this report, *CI* is used as a general term for all configuration items—hardware, firmware, or software. *Computer software CI* is only used to specify a computer software configuration item.

[3] Configuration management terms used in this report are defined in the Glossary. For a more complete collection of definitions that apply to configuration management, refer to Appendix A of *Implementing Configuration Management* (Buckley, 1993).

maintenance of the documents that identify and define the baseline of a CI and the overall system.

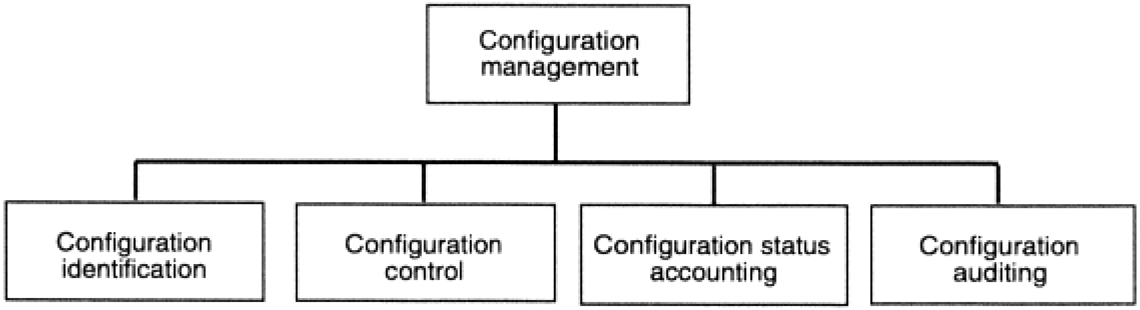


Figure 4-1
Major divisions of configuration management. Source: Buckley, 1993 IEEE.

- *Configuration control*: systematic proposal, justification, evaluation, coordination, approval, or disapproval of proposed changes and the implementation of all approved changes to the configuration of each CI and the documentation that identifies the configuration of the CI.
- *Configuration status accounting*: recording and reporting the implementation of changes to the configuration and its identification documents.
- *Configuration auditing*: checking a CI or system for compliance with the identified configuration.

These functions are performed to manage the configuration of explosives-detection equipment throughout its life cycle.

Configuration Identification

Configuration identification involves selection of CIs and maintenance of the documents that identify and define the baseline configuration of such an item or the overall system (e.g., an EDS). This includes the determination of the types of configuration documentation for each CI—the issuance of unique identifiers (e.g., serial numbers) affixed to each CI and to the technical documentation that defines the CI's configuration. A configuration baseline is the documented configuration of CIs and of the equipment as identified at a particular point in the life cycle of explosives-detection equipment. Definition of the baseline configuration requires documenting the physical and functional characteristics of each CI, as well as the configuration of the items within a system. The manufacturer of explosives-detection equipment is likely to identify several baselines throughout the life cycle of the equipment. Definition of the baseline of explosives-detection equipment (including individual CIs) at the time of certification (a certification baseline) would provide a mechanism for the manufacturer and the FAA to track the *degree and criticality* of changes to the equipment. Here "degree" refers to the extent of the change (e.g., localized versus all encompassing) and "criticality" refers to the importance of the item being changed to system performance. For example, changing the configuration of the x-ray detector in an x-ray-based EDS should receive a more thorough review than changing the color of the external cabinet.

Configuration Control

Configuration control, sometimes referred to as change management or change control, is the set of management functions necessary to ensure that compatibility is maintained between all items of a system whenever any single item is changed (Blanchard, 1986). This includes configuration control of a CI (e.g., an x-ray detector) after establishment of the configuration baseline. Changes in configuration are not uniform in their degree or criticality, and, therefore, classifying the impact of a software, firmware, or hardware change is crucial to determining the extent of verification (up to and including recertification) that would be required. Figure 4-2 describes the basic steps in addressing changes to manufactured equipment.

Classifying the impact of a change on detection performance and the potential need for recertification is a crucial function. Many companies establish a configuration-control board to evaluate each change in terms of its impact on other configuration items prior to a decision on whether or not to incorporate a change. The concept of a configuration-control board is discussed in more detail in Chapter 5.

Configuration Status Accounting and Auditing

Configuration status accounting involves recording and reporting proposed and approved changes to the baseline configuration of a CI. This includes a record of the approved CI documentation and identification numbers, the status of proposed changes to CI configuration, and the implementation status of approved changes. A configuration audit is the process of reviewing a CI or system for compliance with the identified configuration.

As suggested above, the control function of configuration management is to subject all changes to a CI to review and approval by authorized personnel. Configuration status accounting and auditing are tasks that must be diligently performed to maintain configuration control. The description of

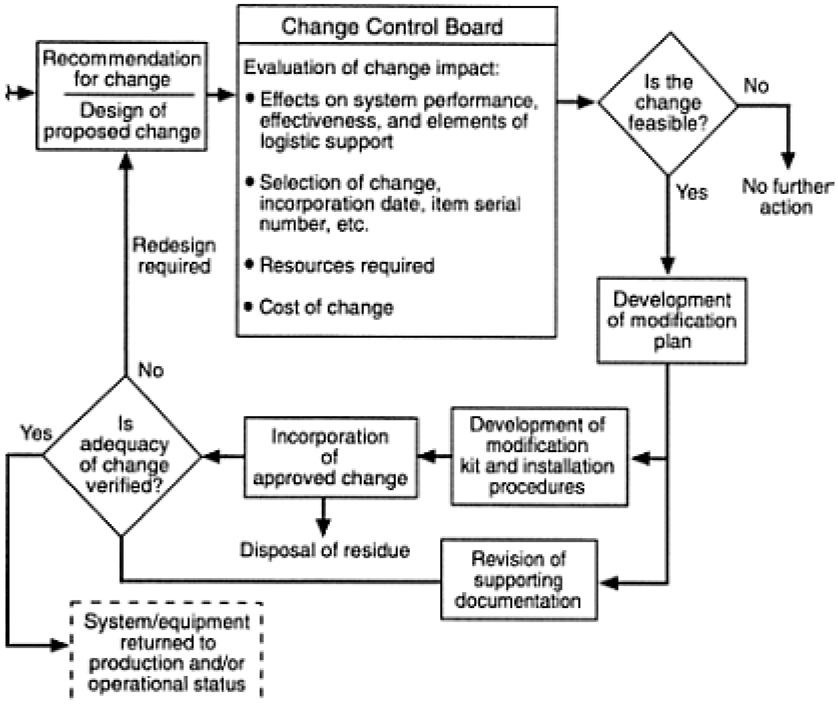


Figure 4-2 Graphical depiction of configuration control. Source: LOGISTICS ENGINEERING AND MANAGEMENT 5/E by Blanchard, Benjamin S., 1998. Adapted by permission of Prentice-Hall, Inc., Upper Saddle River, N.J.

how configuration management will be implemented is documented in a configuration management plan. Several software-based configuration management tools are available to aid in the control task of a configuration management plan, some of which facilitate automated control of CIs.

Configuration-Management Tools[4]

There are a variety of software tools that are useful for establishing and maintaining a configuration management plan. Not all configuration management tools are the same. They are derived from different concepts, have different architectures, and are designed to address a variety of user requirements. Given that there are several tools in the marketplace, selecting the appropriate configuration management tool to meet the needs of the FAA as well as manufacturers of explosive-detection equipment is not a trivial problem. Based on user needs, business goals, and long-term plans, the proper configuration management tool may vary from one manufacturer to another, yet all of these tools may still meet the requirements of the FAA.

Configuration management tools have matured over the past ten years. The amount of functionality, their quality, their useability, and their platform coverage have been greatly improved. The tools can provide the necessary automation support to implement a configuration management plan. Current configuration management tools can be categorized into three classes according to their functionality (Figure 4-3). These tools can be delineated in the following manner:

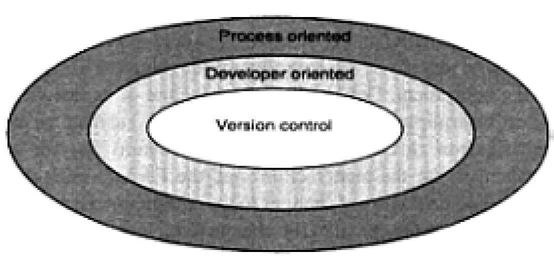


Figure 4-3 Classes of configuration management tools.

[4] This subsection is an overview of configuration management to set the context for recommendations regarding configuration management that are made in this report (see Chapter 5). This subsection is not meant to be a complete tutorial on the subject. For more information please refer to references on the subject such as Buckley (1993) or Burrows et al. (1996).

- *Class 1 -Version-control tools*: individual versions of objects, such as source code, executables, graphics, x-ray sources, detectors, are archived. Simple problem tracking, if any, and limited parallel development may be supported.
- *Class 2 -Developer-oriented tools*: these include version-control capabilities as well as supporting the many needs of teams of developers and managers in parallel development, creating, merging, changing, and releasing products for distribution.
- *Class 3 -Process-oriented tools*: these include version-control capabilities, at least some of the developer-oriented capabilities, the ability to automate the software-flow life cycles, customize the *out-of-the-box* process model, and provide an integrated approach to change management where problem tracking is associated with the code.

Class 3 tools typically have more functionality than Class 2 and integrate Class 2 functionality as part of the tool's infrastructure. Similarly both Class 2 and 3 tools have more functionality than Class 1.

It is likely that the market will eventually demand a uniform (or standard) model of functionality for configuration management tools. As vendors of the tools move toward a uniform model, the classes could disappear so that a single-standard class of tools would support all configuration management needs. Start-up companies, however, may not require all the functionality that such a standard tool may have and might support a market for lower-cost configuration management tools with less functionality. Then, as the company continues to develop and their demands of a configuration management tool grow, it may require a more sophisticated tool. Given the dynamic nature of the configuration management tool industry and the variance in tool user needs, it would not be appropriate to recommend a specific tool at this time. For examples of currently available configuration management tools please refer to Appendix B.

As part of their overall quality systems, the panel recommends that each stakeholder use an appropriate level configuration management tool.

PERFORMANCE VERIFICATION

It could be argued that, when comprehensive and flawlessly performed, configuration management alone could guarantee uniform performance of subsequent copies of EDS. In practice, however, it is impossible to define and control every critical parameter in a manufacturing process or to predict the effect of every change on explosives-detection performance. Therefore, a means of verifying the performance of an EDS is needed to complement the configuration management plan in ensuring operational performance.

Performance verification is defined as the process of verifying that explosives-detection equipment complies with the requirements allocated to it. For example, during the research phase performance verification might include verifying that the proper x-ray attenuation coefficient is measured for a known test material. For deployed (or to-be deployed) EDSs, performance verification might involve testing to determine whether or not the EDS has a similar probability of detection (P_D) and probability of false alarm (P_{FA}) to that of the latest configuration certified by the FAA. For noncertified equipment, performance verification might test to verify that deployed equipment performs at the same level it did during FAA baseline testing (see below for discussion of types of testing).

The panel found it useful to define seven levels of testing that might take place during the life cycle of an EDS: precertification, certification, baseline, qualification, verification, monitoring, and self-diagnosis (see Table 4-1). Although other types of testing may be undertaken by the FAA, manufacturers, or end users, the seven listed above are the

TABLE 4-1 Seven Proposed Testing Levels during the Life Cycle of an EDS

Test Level	Purpose	Location	Test Objects	Frequency
Precertification	Determine if technology is ready for certification testing.	Manufacturer's site	Test articles	Once[a]
Certification of an EDS	Determine if technology performance is at certification level.	FAA Technical Center	Primary standard bag set	Once[a]
or Baseline	Establish baseline performance for noncertified equipment.	FAA Technical Center	Primary standard bag set	Once[a]
Qualification	Verify the performance of an individual manufactured unit to qualify that unit for deployment.	Manufacturer's site	Secondary standard bag set and test articles	Once[a]
Verification	Verify the performance of an individual deployed unit to confirm that performance is at qualification level.	Airport	Secondary standard bag set	At specified occasional intervals
Monitoring	Verify critical system parameters to confirm the consistency of system performance.	Airport	Test articles	At specified frequent intervals
Self-diagnosis	Verify that subsystem parameters are operating according to specifications for continuous "system health."	Airport	None	Continuous

[a]May require retesting until the unit passes the specified test.

ones related to certification and certification maintenance. The FAA's current certification documentation specifies the testing protocols and test objects to be used for the first three test levels, i.e. precertification, certification, and baseline (FAA, 1993). The remaining four test levels—qualification, verification, monitoring, and self-diagnosis follow manufacturing and airport deployment and have thus far not been included.

To verify detection performance of bulk explosives-detection equipment at manufacturing sites and in airports will require two integrated steps: (1) definition of performance specifications for these environments, and (2) development of test protocols that are practical at manufacturing sites and in airports, including the development of appropriate test objects. In both cases performance specifications are central to effectively defining a performance-verification protocol.

Performance specifications must be validated for performance verification to be effective. That is, the performance specifications for explosives-detection equipment must represent the performance required to detect explosives in checked baggage. Performance verification and validation will likely be challenging due to variations in explosive threats and changes in explosives-detection equipment design, manufacture, and operational usage. As threats and system configurations change, a means to verify the performance of explosives-detection equipment at airports and manufacturing sites is needed to ensure that performance specifications continue to be met after such changes occur.

Precertification testing allows the FAA to guide manufacturers in development of new equipment to meet the requirements of explosives-detection certification testing. At this stage of development the FAA and the manufacturer should have established a mutual understanding of the requirements and the technology being tested. The panel recommends that specified parameters critical to performance be monitored and recorded during precertification testing. At the same time, the manufacturer may take advantage of this testing opportunity to record the response to any of their in-house test articles to enhance their ability to develop future systems quickly and cost effectively.

FAA Certification Testing

The FAA certification process involves testing explosives-detection equipment that has an identified baseline configuration and that has passed precertification testing at the manufacturing facility[5] (FAA, 1993). Certification testing is performed at the FAA Technical Center using, as a primary standard, bags of different sizes and shapes with a variety of explosives located at different positions in the bag and with a variety of normal bag contents that may interfere with detection of explosive materials. Special facilities have been constructed at the FAA Technical Center to allow real explosive materials to be handled and tested. The results of these tests include a figure of merit for the probability of detection (P_D), for the probability of false alarms (P_{FA}), and for the baggage throughput rate.

Testing in Airports

In 1995 the FAA Technical Center developed a test and evaluation master plan in support of their Baggage Inspection System Airport Operational Demonstration Project (FAA, 1995). The purpose of this demonstration project was to assess the operational feasibility, suitability, and effectiveness of the FAA-certified InVision CTX-5000-SP EDS and, therefore, to support deployment decisions. The demonstration project, however, does not define performance-verification protocol for use in routine testing of explosives-detection equipment in airports. The knowledge gained during this demonstration should be incorporated into the development of operational requirements and a performance-verification protocol including development of appropriate test articles.

Testing and Technology

The technology for detecting explosives in baggage must be capable of detecting an explosive and notifying the operator of the potential presence of a threat. As with many technologies, however, the performance of explosives-detection equipment is subject to practical limitations. These limitations arise because the equipment performs a complicated task with incumbent confusion (or noise), which results from the variety of baggage that passes through the system, from the nonthreat contents within each bag and the variability of the measurement equipment. In addition, different technologies for explosives detection will have different critical performance parameters. Thus, the specifics (e.g., test articles, critical system parameters, etc.) of performance verification are likely to vary from one explosives-detection technology to another. The general performance-verification protocol (e.g., logistics), however, should apply to several different technologies.

In developing a performance-verification protocol, the characteristics that define explosives-detection equipment must be considered. Any specific performance-verification protocol must be tailored to the particular type of equipment being tested, but an early identification of the different components and subsystems making up the equipment (as discussed in Chapter 3) will increase the efficiency and rigor of the protocol.

[5] In cases where manufacturers do not have the license or facilities to handle explosive materials, portions of precertification testing may be conducted (by the manufacturer) at the FAA Technical Center using a bag set that is entirely different from the bag set used for certification testing. In addition, precertification testing typically includes operational testing at airports using actual passenger baggage (without explosives or simulants) to collect false-alarm and throughput rate data.

Approaches to Test and Evaluation

As indicated above, the FAA certification process relies almost entirely on test and evaluation, at the FAA Technical Center, of a complete unit of explosives-detection equipment (FAA, 1993). As such, certification testing incorporates all of the factors that contribute to the spread of the decision variables (physical parameters measured), as depicted in Figure 4-4. (For a complete discussion of the threat-decision paradigm, see Appendix C.) The inclusion of all factors during a test is not the only, nor the most efficient, way to evaluate the performance of explosives-detection equipment.

The capability of explosives-detection equipment to detect explosives can be estimated through the measure of physical parameters associated with operational subsystems of the equipment. For example, equipment using image data for classification of objects may be partially evaluated through the measure of parameters such as contrast sensitivity, system spatial resolution, and the quantity and character of noise and related parameters (ICRU, 1995). This International Commission on Radiation Units and Measurements report describes a means of evaluating the random fluctuations due to the statistical processes by characterizing the manner in which the noise power is distributed over spatial frequency. Although this measure represents a fairly sophisticated measure of noise, given the digital nature of the image from a CT system, there is no reason why similar measures could not be performed on an x-ray CT-based EDS system at the factory, the FAA Technical Center, or the airport facility. The American Association of Physicists in Medicine (AAPM) also provides some candidates for test articles and test protocols to be used to make the performance measurements related directly or indirectly to contrast, spatial resolution, and the quantity and character of noise (AAPM, 1993). In addition to the test articles described in this AAPM report, several commercial sources[6] are available for purchasing test articles for making similar measurements that have been used to test medical CT systems. Tests using such articles could be performed in the factory or at an airport.

For an x-ray CT-based EDS system in the airport environment, the resolution of alarms typically requires that an operator scrutinize an image and, therefore, will depend on the quality of the image on the system's video monitor. Any test and evaluation plan must include this component of the entire imaging system. The approach in the medical imaging community in testing this component is to use digital test patterns such as the Society of Motion Picture and Television Engineers (SMPTE) digital test pattern (Gray et al., 1985). Again, because this type of test is straightforward, an equivalent test could be used not only in the factory but at the airport facility to test the display device on the CT-based EDS system.

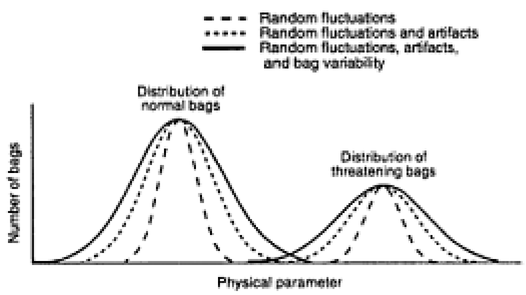


Figure 4-4 Factors contributing to the spread of the measured physical parameter(s).

Manufacturers of explosives-detection equipment based on other technologies could identify parameters indicative of their system's performance. The manufacturer has unique knowledge about which critical parameters and test articles are appropriate for their system, but it is to all stakeholders' advantage to identify these at the precertification stage and to maintain them throughout the life cycle of the EDS.

In addition to relating explosives-detection equipment performance to specific system parameters, there is a need for the FAA to continue development of materials that simulate explosives. These simulants could be used in a secondary standard bag set that yields test results that correlate strongly with the results obtained from testing with the primary standard bag set (see, for example, Annex II in NRC, 1993). These simulants must be matched to specific explosives and to specific explosives-detection technologies.

Similar to how the FAA controls the explosives used in the primary standard bag set, simulants used in the secondary standard bag set need to be controlled to ensure that they continue to accurately represent the explosive threat (i.e., explosives at threat level). Factors that need to be considered in controlling the simulants include changes to the primary threat and the shelf life (e.g., degradation of chemical and physical properties of simulants over time) of the simulants. Furthermore, the configuration of the secondary bag set would need to be controlled.

QUALITY SYSTEMS AND STANDARDS

> The total quality system is the agreed company-wide and plant-wide operations work structure, documented in effective, integrated, technical, and managerial procedures, for guiding the coordinated actions of the work force, the machines, and the information of the company and plant in the best and most practical ways to assure customer quality satisfaction and economical costs of quality (Feigenbaum, 1983).

[6] Some sources that the panel is aware of are Computerized Imaging Reference Systems, Inc., Norfolk, Va.; Nuclear Associates, Carle Place, N.Y.; Gammex RMI, Middleton, Wis. This list is provided as a resource only; the panel does not endorse any specific company or product.

A quality system is a model for quality assurance in design, development, production, installation, operation, and maintenance. The quality system balances basic principles of quality control such as configuration management and performance verification—facilitating the synergistic use of these tools to ensure the performance of explosives-detection equipment. An effective, thorough quality system is crucial to maintaining the performance of explosives-detection equipment.

For the operational performance of explosives-detection equipment to be ensured during its life cycle, the key attributes of a quality system must be defined and supported by the management of each stakeholder, as well as the personnel responsible for quality assurance. Adequately addressing the key attributes of a quality system, as defined in Box 4-1, have been found to be crucial to the success of a quality system.

Standards for Panel Consideration

There are likely as many quality systems in practice as there are organizations that use quality systems. Each one is tailored to meet the specific needs of a particular organization. The panel considered the following quality standards from government sources and commercial industry for the FAA to use in developing its framework for a quality management program:

- U.S. Department of Defense standard MIL-Q-9858A (DOD, 1963)
- FAA Type Certification (for certification of airplanes and components; 14 Code of Federal Regulations, 1997)
- FDA's Good Manufacturing Practices (21 Code of Federal Regulations, 1995)
- ISO 9000 series of quality system standards (ISO, 1994)
- North Atlantic Treaty Organization standards AQAP-130 (NATO, 1993a)and AQAP-131 (NATO, 1993b)

In addition, the panel considered the use of a quality standard developed by the FAA in-house, as has been done by various private companies.

The U.S. Department of Defense and the North Atlantic Treaty Organization quality systems and standards were

BOX 4-1 ATTRIBUTES OF AN EFFECTIVE QUALITY SYSTEM

Quality Planning-defining methods that will ensure the compatibility of the design, the production process, installation, servicing, inspection, and test procedures and the applicable documentation. **Design Control**-establishing and maintaining a process to control and verify the design of the product to ensure that the specified requirements are met. This attribute, along with the attribute of *document and data control*, is the basis for the activities that are defined in configuration management.

Document and Data Control-establishing and maintaining a process to provide documentation, which identifies the key quality activities, throughout the organization to properly design, plan, and perform the necessary work.

Process Control-identifying and planning of the production, installation, and servicing processes that directly affect the quality of the product. Compliance with reference standards and regulatory requirements is accounted for by integrating them with the processes that are to be controlled.

Inspection and Testing-establishing and maintaining procedures for performance verification to verify that the specified requirements are being met. This activity takes into account the receipt of materials and processes, the in-process activities during the build of the product, and the final review of the product before delivery. These levels of inspection and testing correlate the designed configuration of the system with the as-built configuration and verify that the product performs as specified by regulatory and customer requirements.

Control of Inspection, Measuring, and Test Equipment-establishing and maintaining the appropriate equipment with which to monitor the entire process and measure the results of performance-verification activities.

Control of Nonconforming Product-establishing and maintaining procedures and processes by which products that do not conform to the specified regulatory or customer requirements are removed from the process and prevented from being accidentally installed and delivered.

Corrective Action-establishing and maintaining a process to identify the origin of a problem (e.g., product performance or manufacturing processes) and implement a solution to prevent problem recurrence.

Training-establishing the job proficiency levels required for the manufacture, operation, and maintenance of a product (including configuration management and performance verification) and providing appropriate information, instruction, and resources to raise personnel skill levels to ensure that customer and regulatory quality requirements are met.

eliminated from further consideration by the panel because they have been (or are in the process of being) canceled without replacement, with the caveat that commercially available quality standards are to be used as a model for developing future quality systems. The panel, furthermore, eliminated from consideration the development (by the FAA) of a unique non-standards-based quality system for use by all manufacturers of explosives-detection equipment because commercial-quality standards exist that could serve the needs of the FAA, the manufacturers, and the end users; the development of a new, unique quality system is unnecessary.

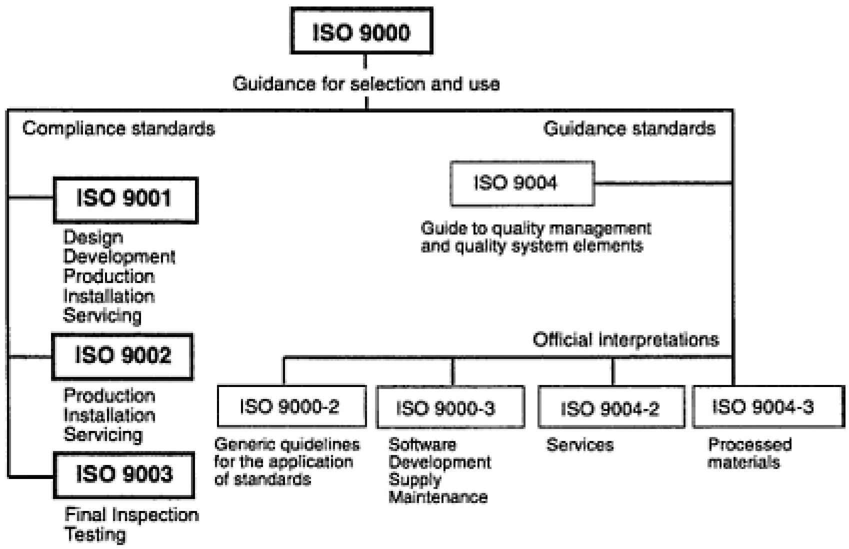


Figure 4-5 ISO 9000 standards and guidelines. The emphasis of this report is on the compliance standards ISO 9001, ISO 9002, and ISO 9003.
Source: Lockheed Martin Corporation.

Based on the expertise of the panel members, testimony from outside experts, and review of relevant literature, the panel critically assessed three quality standards for use by the FAA:

1. FAA Type Certification (14 Code of Federal Regulations, 1997)
2. the Food and Drug Administration's Good Manufacturing Practices (21 Code of Federal Regulations, 1995)
3. the ISO 9000 series of quality system standards (ISO, 1994)

Each of these quality standards has the following characteristics:

- It requires that a documented quality system be in place.
- It requires a documented method of configuration management that incorporates the needs of the stakeholders (i.e., the FAA, manufacturers, air carriers, and airports).
- It requires that the manufacturer be accountable for the product up to and including delivery of the product to its operational environment. Included in this accountability is the provision of a maintenance plan and information regarding product upgrades.

Because of the flexibility in application, the availability of companies that provide third-party monitoring and reporting, and the global move toward the ISO 9000 series of quality standards, the panel believes that ISO 9000 has the most promise for addressing the quality system needs of the FAA, as discussed in the next subsection. Discussion of FAA Type Certification and the FDA's Good Manufacturing Practices can be found in Appendix D.

ISO 9000 Series Quality Standards

The ISO 9000 series international standard specifies quality system requirements for use when a supplier' s capability to design and supply products that meet a designated standard needs to be demonstrated (ISO, 1994). The ISO 9001 Compliance Standard covers design, development, production, installation, and servicing. ISO 9002 covers only production, installation, and servicing, and ISO 9003 covers final inspection and testing (see Figure 4-5). ISO 9001 and ISO 9002 standards are used to guide several domestic and foreign organizations. The ISO 9000 series quality standards have four basic requirements[7]:

[7] The requirements listed for ISO 9001 refer to the "manufacturer" as the actor; the panel believes that these requirements are equally applicable to the FAA and to the users of explosives-detection equipment.

1. Executive management of the manufacturer must be responsible for defining and documenting its policy for quality. This policy should be relevant to the manufacturer's organizational goals; the needs of its customers; and in this case, the requirements of the FAA. A key requirement of the ISO 9000 series standards is that senior management, not department-level management, is responsible for the quality system.
2. To provide structure and consistency to the quality system, all basic processes (e.g., design, contract review, procurement, manufacturing, inspection, and testing) must be documented.
3. The quality system should be flexible in application, while at the same time providing a consistent structure for manufacturing employees to follow.
4. Performance verification (confirmation that the equipment fulfills the specified requirements) and validation (confirmation that the specified requirements satisfy customer/regulator needs) are required throughout the life of the product.

Part of the ISO 9000 series quality standards is a set of guidance documents that can be used to help interpret and tailor the requirements of the standards to a specific business (ISO, 1994):

1. ISO 9000-1. Quality management and quality-assurance standards (Part 1: Guidelines for selection and use)
2. ISO 9000-2. Quality management and quality-assurance standards (Part 2: Generic guidelines for the application of ISO 9001, ISO 9002, and ISO 9003)
3. ISO 9000-3. Quality management and quality-assurance standards (Part 3: Guidelines for the application of ISO 9001 to the development, supply, and maintenance of software)

There are several advantages to using the ISO 9000 series quality standards as a basis for the FAA to develop its quality system for maintaining consistency in the regulation of EDSs. A quality system that meets the intent of (is consistent with) ISO 9001 or ISO 9002 will provide the necessary framework to maintain consistency such that the FAA could regulate the manufacture of EDSs. Furthermore, the manufacturer of EDSs is allowed the flexibility to develop a quality system that supports its specific product and processes. At the same time, ISO 9001 and ISO 9002 provide the FAA with a standard mechanism by which to audit, and thereby regulate, several different manufacturers through a third party at no cost to the FAA. Finally, ISO 9001 certification or registration will likely be necessary for explosives-detection equipment manufacturers to compete in the international marketplace.

The flexibility of the ISO 9000 series quality standards can, however, result in the development of a quality system that may not be sufficient for EDS manufacture. That is, the manufacturer's quality system may not comprehensively track the production of the EDS, yet the process in place will still meet the intent of the ISO 9000 series quality standards. This point is crucial, because although a quality audit will verify that the manufacturer is following its quality system, it does not validate that the quality system results in the production of a certifiable EDS. It will be critical for the FAA, the manufacturers, and the users to work together as experience is gained from deploying EDSs to ensure that appropriate measurements and quality systems are in place. Also worthy of consideration is the fact that the auditing process required to gain ISO 9000 certification does incur expenses, and this is discussed in Appendix E. Because the auditing process is crucial to determining that the quality system of each stakeholder is functioning correctly, the panel emphasizes that the cost of performing periodic audits is part of regulating and complying with regulation, and must be considered an integral part of the cost of certification.

5

Life-Cycle Management Plan

Chapter 2 outlined the minimum requirements for a credible, flexible, and effective regulatory strategy. Subsequent chapters introduced explosives-detection technologies, configuration management, performance verification, and quality systems. This final chapter returns to the requirements addressed in Chapter 2 and presents a management plan that the panel believes will meet the requirements of all stakeholders. In addition, details of the panel's findings and conclusions that led to the selection of this strategy are presented. Finally, the panel's recommended life-cycle management plan is presented.

EXPLOSIVES-DETECTION EQUIPMENT LIFE CYCLE

The life cycle of explosives-detection equipment can be delineated in several manners. The panel identified the following five broad phases in the life cycle of explosives-detection equipment, as depicted in Figure 5-1:

- the *research phase*, which includes basic research and testing up to and including proof of concept
- the *engineering phase*, which includes the development of the manufacturer's original design and modifications to that design and the completion of a production-representative system for certification testing by the FAA
- the *manufacturing phase*, which includes pilot production, certification (performance and documentation of precertification testing and certification testing at the FAA Technical Center), and manufacturing (which includes the assembly and testing of reproductions of systems that have been certified and the incorporation of approved improvements and upgrades to the certified design)
- the *operational phase*, which includes initial deployment and normal use and operation
- the *retirement phase*, which includes removal and disposal of a system

Each of the above life-cycle phases encompasses quality assurance, performance verification, and configuration management of hardware, software, and firmware.[1] However, as shown in Figure 5-2 only the manufacturing and operational phases receive oversight by the FAA through the management plan because these phases are where the FAA acts in its role to ensure proper explosives-detection performance (through certification or through purchase for airport deployment) and where changes to design or configuration that affect detection performance of manufactured units in the airport are likely to occur. The actions taken by the stakeholders during each life-cycle phase regarding quality assurance, performance verification, and configuration management are shaped by the needs of the stakeholders, which are influenced by external developments such as emerging technologies, changing threats, and economic constraints. Therefore, the evolution of explosives-detection equipment is dependent on actions taken by or for the stakeholders as a result of external developments. The delegation of responsibility for such actions should be based on the responsibilities and expertise of each stakeholder, as suggested in Figures 5-3, 5-4, and 5-5.

MANAGEMENT PLAN

A life-cycle management plan, or more generally, a *management plan* , describes a strategy to integrate all the aspects of manufacturing and deployment. Such a plan is needed because changes are a normal part of the life cycle of any manufactured product. Examples of changes that may affect the performance of explosives-detection equipment include

[1] Firmware is software, inclusive of programs or data, that has been permanently written onto read-only memory (ROM) or programmable read-only memory (PROM). Firmware is a combination of software and hardware. Firmware is included as an item that should be under configuration management, because, like hardware and software, changes made to firmware can alter the performance of explosives-detection equipment.

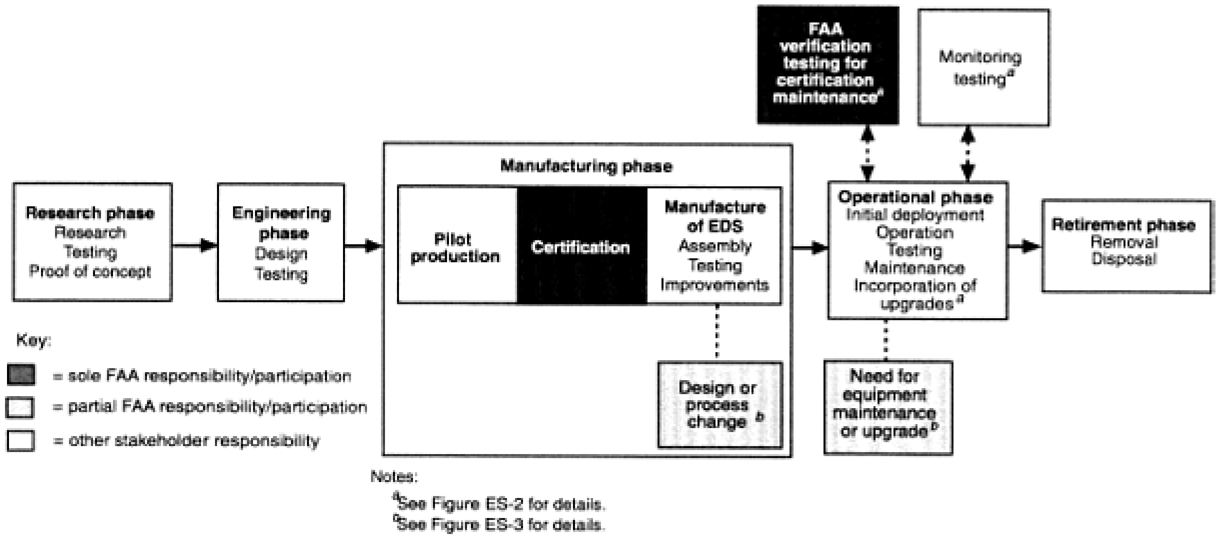


Figure 5-1
Five phases in the life cycle of an EDS.

- design changes in a subsystem
- nominal production and process variations
- manufacturing changes in hardware, software, and firmware and improvements to these elements
- software, firmware, or hardware upgrades to explosives-detection equipment already in service
- repair and replacement of an equipment module at the installation site (e.g., at the airport)
- incorporation of new components from a different vendor
- relocation of explosives-detection equipment from one installation site to another
- in-service degradation and aging

These factors can cause the performance of an EDS to vary from certification requirements and noncertified explosives-detection equipment to vary from its baseline performance. Therefore, the FAA should employ a management plan that specifies the methodologies for configuration management and performance verification to ensure an acceptable and known level of confidence in the performance of explosives-detection equipment.

The panel has devised a plan—the life-cycle management plan—that it believes would address the needs of the FAA to ensure detection performance while also addressing the needs of the manufacturers and users to pursue their business opportunities. The panel recommends that this plan reside with and be maintained by the FAA. This plan defines and documents the FAA's configuration-management, performance-verification, and quality-assurance requirements for the following stakeholders:

- the FAA during certification or baseline, qualification, and verification testing of explosives-detection equipment (this would include control of test objects, procedures, and test results and accompanying documentation)
- explosives-detection equipment manufacturers during the certification, manufacturing, and operational phases of the life cycles
- the air carriers and other end users, with regard to deployed explosives-detection equipment, during the operational life cycle (this would include control of operating and maintenance procedures)

In essence, the goal of the management plan is to provide a systematic framework for the FAA to define configuration-management, performance-verification, and quality system requirements; a mechanism to meet these requirements; a means to measure if the requirements are being met; and a method to communicate with other stakeholders—all to ensure performance throughout the life cycle of explosives-detection equipment. It is recognized that over time there may be changes in the threats to aviation security and in the equipment that is used to detect them. Thus, ideally, the management plan adopted by the FAA should be sufficiently robust and flexible to accommodate a range of scenarios as these scenarios shift over time.

The FAA already has documented procedures that address much of what is suggested above. For example, the FAA's *Management Plan for Explosives Detection System Certification Testing* (FAA, 1993) and their *Technical Center Baggage Inspection System: Airport Operational*

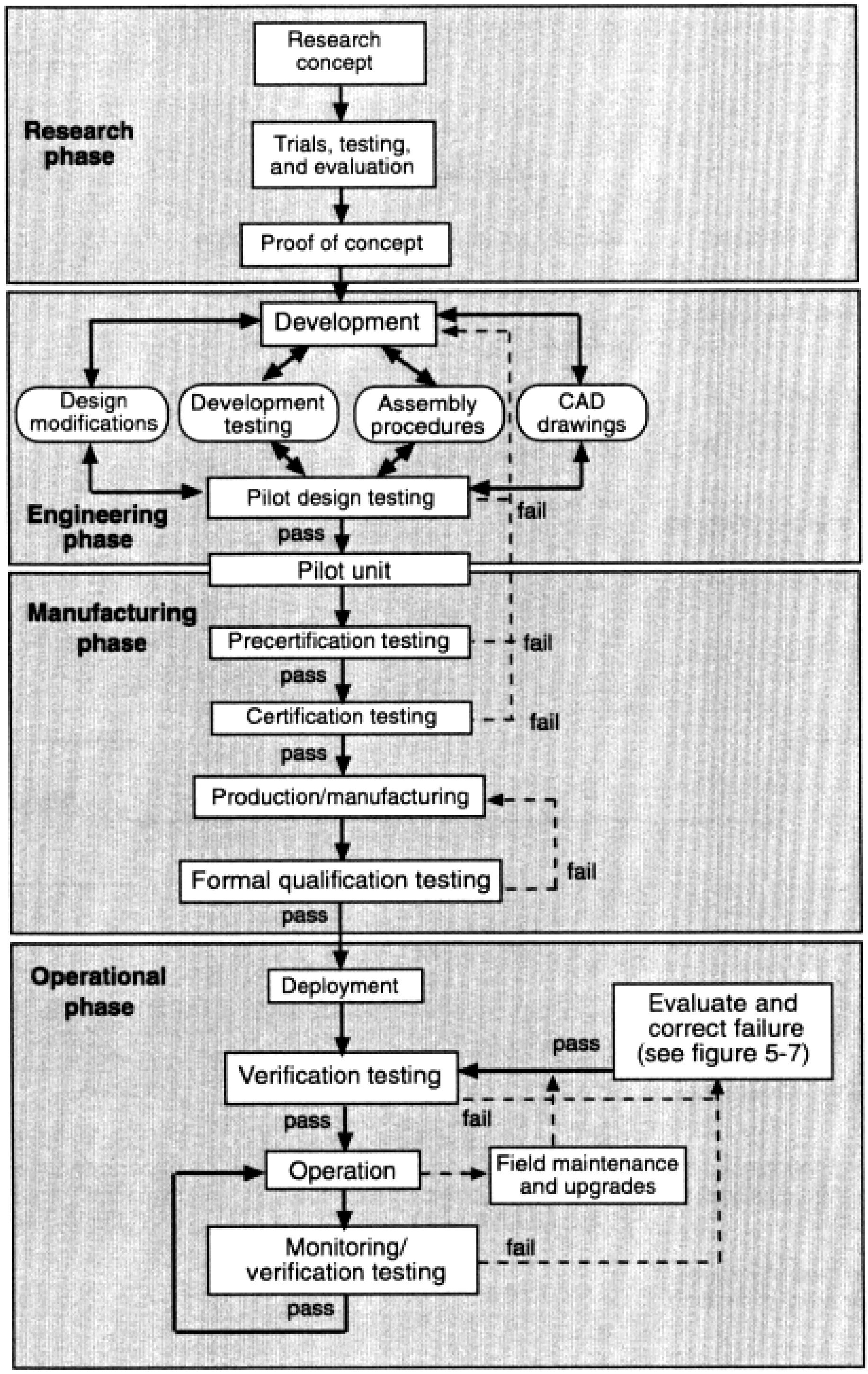
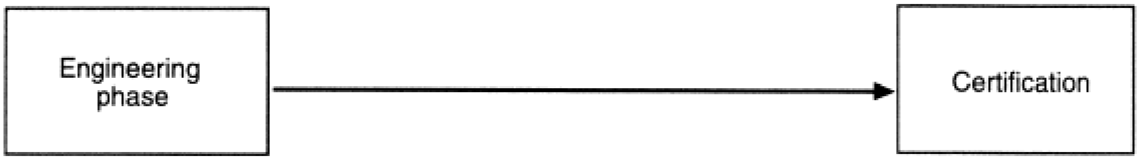
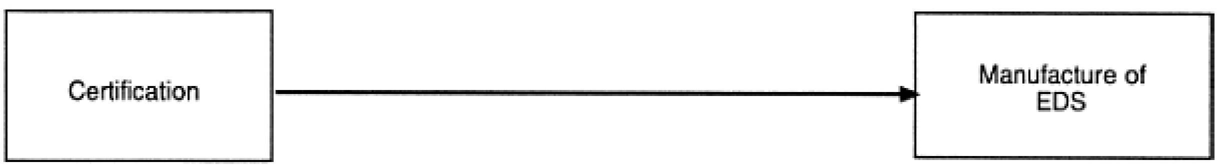


Figure 5-2
Activities over the life cycle of explosives-detection equipment.



FAA	Manufacturer	User
Develop primary standard bag set.	Identify system baseline configuration.	Participate in and facilitate precertification airport testing for explosives-detection technology.
Demonstrate that a quality system is used for all certification test objects and test protocols.	Identify critical system parameters, including acceptable values and ranges.	
Ensure that a quality system is in place for the manufacturing and operational life-cycle phases of an EDS.	Demonstrate a quality system for manufacturing, including a change control process.	
Develop secondary standard bag set.	Demonstrate completion of precertification activities.	

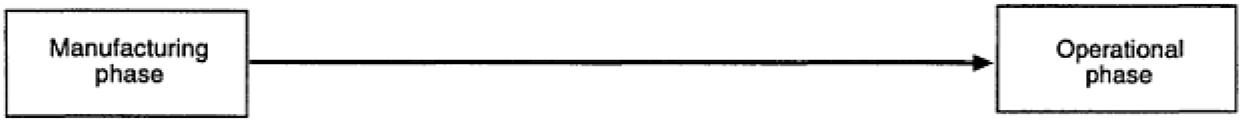
Figure 5-3
Responsibilities of stakeholders for moving from the engineering phase to certification.



FAA	Manufacturer	User
Ensure the development of a secondary standard bag set.	Develop proposed manufacturing change classification levels and procedures and facilitate acceptance by other stakeholders.	Participate in the development of manufacturing change classification levels and procedures.
Validate secondary standard bag set.		
Participate in the development of manufacturing change classification levels and procedures.	Participate in the development of performance standards, test protocols, and test objects for qualification testing.	Participate in the development of performance standards, test protocols, and test objects for qualification testing.
Establish performance standards and test protocols for qualification testing.		
Validate test objects for qualification testing.		

Figure 5-4
Responsibilities of stakeholders for moving from certification to the manufacture of an EDS.

Demonstration Project Test and Evaluation Master Plan (FAA, 1995), outline several of the FAA's existing documented procedures that are appropriate for ensuring the performance of explosives-detection equipment. The panel endorses these plans and recommends that the FAA implement the life-cycle management plan described above, which will provide a highly visible formal structure to follow existing guidelines as well as those recommended in this report.



FAA	Manufacturer	User
Establish performance standards and test protocols for validation and monitoring testing.	Participate in the development of operational configuration change process.	Demonstrate quality systems for EDS testing, maintenance, and upgrades.
Validate test objects for validation and monitoring testing.	Participate in the development of performance standards, test protocols, and test objects for verification and monitoring testing.	Develop an operational configuration change process.
Participate in the development of operational configuration change process.		
Perform periodic verification testing and maintain data.	Notify FAA and users of maintenance requirements and opportunities for upgrades.	Participate in the development of performance standards, test protocols, and test objects for verification and monitoring testing.
Perform qualification testing with manufacturer.	Maintain self-diagnostics data.	Perform routine maintenance.
	Maintain configuration documentation of units to be deployed.	Perform monitoring testing and maintain data.
		Maintain configuration documentation of units in airports.

Figure 5-5
Responsibilities of stakeholders for moving from the manufacturing phase to the operational phase.

To be effective, the FAA's management plan must address the specific needs of each stakeholder during the certification, manufacturing, and operational phases of the explosives-detection equipment life cycle. The management plan should be structured to encourage industry to continue to develop and improve explosives-detection equipment, while at the same time assuring the regulator (FAA) and the users (air carriers and airports) of the performance of such equipment.

As the regulatory agency responsible for air safety and security, the FAA must retain their authority to establish the performance specifications for explosives-detection equipment and to establish airport testing protocols and schedules. These tests are likely to be performed in airports by non-FAA personnel on equipment designed and manufactured by independent companies, and so the test protocols and the performance levels must be specified such that they are practical to be carried out by air carrier or third-party personnel. Furthermore, the manufacturers must include the appropriate hardware and software in their equipment designs such that testing personnel can carry out the FAA-mandated tests. Because of the extensive involvement of the manufacturers and users in the testing, these stakeholders should be involved in the development of the management life-cycle plan so that appropriate roles are assigned to the FAA, the manufacturers, and the users.

Preparing performance specifications and testing protocols for deployed explosives-detection equipment will be fundamentally different from, and more difficult than, developing certification standards and test protocols. In developing the performance specifications and testing protocols for the FAA certification testing, the FAA evaluated the threat to aviation security and set amounts and types of explosives that must be detected. Working with air carriers and equipment manufacturers, the FAA set instrument false-alarm and throughput rates that were acceptable to the other stakeholders. Protocols were developed to test equipment against certification specifications. Because the FAA performed the certification tests at the FAA Technical Center, they could also determine the limitations placed by the testing facility on the testing protocols, including testing time and test object availability. In the case of testing deployed explosives-detection equipment, the FAA has little control over the facilities and on the time available at the airports.

Recommendation. The FAA should involve the stakeholders in implementing the generalized framework for the management plan, including

- establishing explosives-detection equipment performance requirements and correlating parameter specifications (tolerances)
- developing a performance-verification protocol suitable for airport testing of explosives-detection equipment
- tailoring performance-verification planning guidelines to specific air terminals, and explicitly identifying the roles of each stakeholder

Finally, it is imperative that best practices be employed throughout the life cycle of explosives-detection equipment. That is, the FAA, the equipment manufacturer, the air carriers or other end users, and the airports should (1) have a well-defined quality system in writing and (2) ensure that everyone within a particular stakeholder enterprise who is involved with the *process* (e.g., testing, manufacturing, or operating explosives-detection equipment) understands and adheres to the written procedures. One resource available to all stakeholders to aid in identifying the best practices used in industry, government, and academia for manufacturing and management is the Best Manufacturing Practices Center of Excellence, as discussed in Box 5-1.

CONFIGURATION MANAGEMENT PLAN

A configuration management plan is a document that defines how configuration management will be implemented for a particular acquisition program or system (DOD, 1995). In this case the program is the FAA's Aviation Security Program, and the system is for detecting explosives. These two issues are dealt with separately below.

Configuration Management of the FAA Aviation Security Program

As discussed above, the FAA is responsible for identifying and documenting threats to aviation security and determining the requirements for explosives-detection equipment. The FAA is also responsible for developing and controlling test protocols for verifying that explosives-detection equipment meets these requirements. Over time, FAA certification requirements, test protocols, and standards will have to change to respond to new threats, as well as to take advantage of new detection technologies. Using the principles of configuration management to track such changes would ensure a means for maintaining records of them for certified and noncertified systems alike.

Recommendation. The FAA should implement a configuration-management plan that focuses on controlling the configuration of

BOX 5-1 BEST MANUFACTURING PRACTICES PROGRAM OF THE OFFICE OF NAVAL RESEARCH

The mission of the Best Manufacturing Practices Center of Excellence is to identify and promote exemplary manufacturing practices and disseminate this information to U.S. manufacturers of all sizes. It is an outgrowth of the Department of the Navy's Best Manufacturing Practices program and was created in 1993 as a joint effort of the Office of Naval Research; the National Institute of Standards and Technology, Manufacturing Extension Partnerships; and the Engineering Research Center of the University of Maryland at College Park. The program provides a national resource to foster the identification and sharing of best practices being used in government, industry, and academia; and to work together through a cooperative effort aimed at strengthening the U.S. industrial base and its global competitive position.

Independent teams of government, industry, and academic experts survey organizations that are ready to share information about their own best processes. Participation in the survey is voluntary and at no cost to the requesting organization. Once the team completes its work, the surveyed activity or organization reviews a draft of the report. Copies of the final report are distributed to representatives of government, industry, and academia throughout the country and entered in the Best Manufacturing Practices database. The information in the reports is designed to help organizations evaluate their own processes by identifying, analyzing, and emulating the processes of organizations that excel in those areas.

Since the inception of the Best Manufacturing Practices program, more than 95 organizations have participated in surveys. A synopsis of each survey is available from the program's website at http://www.bmpcoe.org/. Further detailed information can be obtained by contacting the person identified in each survey or by contacting the Best Manufacturing Practices Center of Excellence at 4321 Hartwick Rd., Suite 400, College Park, MD 20740; 1-800-789-4267.

- documented threat definition
- performance requirements and test protocols for precertification, certification, baseline, qualification, verification, monitoring, and self-diagnostic testing
- test objects, including simulants and primary and secondary standard bag sets
- test results
- test protocols and performance capability categories of noncertified equipment

Recommendation. As a part of the FAA's configuration-management plan, the FAA should, for each of the above items,

- identify the baseline configuration, including identification of configuration items (CIs) using unique identifiers
- track all changes
- identify the criticality of CIs and the degree and criticality of potential changes to them

Configuration Management of Explosives-Detection Equipment

The FAA recognizes the importance of a documented configuration-management plan, as indicated by their stated requirements for manufacturers of explosives-detection equipment who are applying for certification: "The vendor must provide documentation describing the system configuration management and quality assurance plans and practices applied during system development, production, and test and evaluation. This shall include hardware, software, and firmware version tracking and control, test equipment/ tool certification tracking, explosive/simulant validation tracking and documentation up-date/control" (FAA, 1993).

Recommendation. The FAA should continue to enforce its existing guidelines by ensuring periodic third-party reviews of the configuration-management plan and practices of equipment manufacturers. These reviews should include physical-configuration audits (i.e., a technical examination of the EDS to verify that, "as-built," it conforms to the certified baseline) and in-process audits (i.e., an examination to determine if the configuration-management process established by an organization is being followed).

Recommendation. Definition of the baseline configuration of explosives-detection equipment prior to certification provides a mechanism for the stakeholders to determine the degree and criticality of changes to explosives-detection equipment. Therefore, the panel recommends that the FAA require manufacturers of explosives-detection equipment to take the following actions:

- establish the baseline configuration of the explosives-detection equipment, including identification of CIs with unique identifiers, prior to certification (certification baseline)
- have a process in place to determine the degree and criticality of changes in the EDS or noncertified explosives-detection equipment
- notify the FAA of changes in configuration-management practices
- implement version control, inclusive of baseline management, as a minimum requisite for certification

Recommendation. To maintain the configuration of explosives-detection equipment during certification testing, the panel endorses and recommends continued documentation of equipment configuration and changes to this configuration through use of the FAA's *Configuration Log* as described in their 1993 *Management Plan for Explosives Detection System Certification Testing*.

Configuration Control

Ideally, manufacturers of explosives-detection equipment should establish configuration control procedures during the engineering phase. The other stakeholders (FAA and end users such as the airlines or airports) will, however, only be directly involved in change decisions after certification (i.e., during the manufacturing and operational lifecycle phases). For effective configuration control, all of the stakeholders must agree up front to the types of changes to the certification baseline that need to be brought to the attention of the stakeholders prior to implementation (see, for example, Figure 5-6).

Recommendation. All stakeholders (air carriers, FAA, equipment manufacturers) should agree prior to the manufacture or deployment of an EDS on a change classification system and process to ensure that stakeholders are notified of changes as necessary.

The benefits of having a change classification process in place prior to the manufacture or deployment of an EDS include the incorporation of improvements with a minimum of confusion about the role of each stakeholder, the clarification of retesting required to confirm the effects of changes, and the empowerment of each stakeholder to evaluate EDS performance continually and suggest improvements. A typical change classification system ranks changes as follows:

- Class 1 changes are likely to affect system performance.
- Class 2 changes might affect some aspects of system performance.
- Class 3 changes are not likely to affect system performance.

To determine the impact and acceptability of changes to a system, many manufacturers have instituted a change approval process that involves formation of a configuration-control board, which includes representatives from the research, engineering, quality-assurance, marketing, and service areas. The board is the final arbiter of which changes are accepted or rejected. However, as discussed above, the effects of some changes are such that the customer and regulator should have input into the required evaluations and the decision of whether to implement a proposed change. A stakeholders' configuration-control board, involving representatives of the end users (air carriers) and the FAA, would provide a mechanism for such a review, with the manufacturers configuration-control board having the responsibility to ensure that changes of an appropriate degree and criticality are brought before the stakeholders' configuration-control board. The stakeholders' configuration-control board should determine the method of verifying the influence of a proposed change on system performance. In the event that consensus cannot be gained within the stakeholders' configuration-control board, the FAA should act as the final arbiter to resolve the situation.

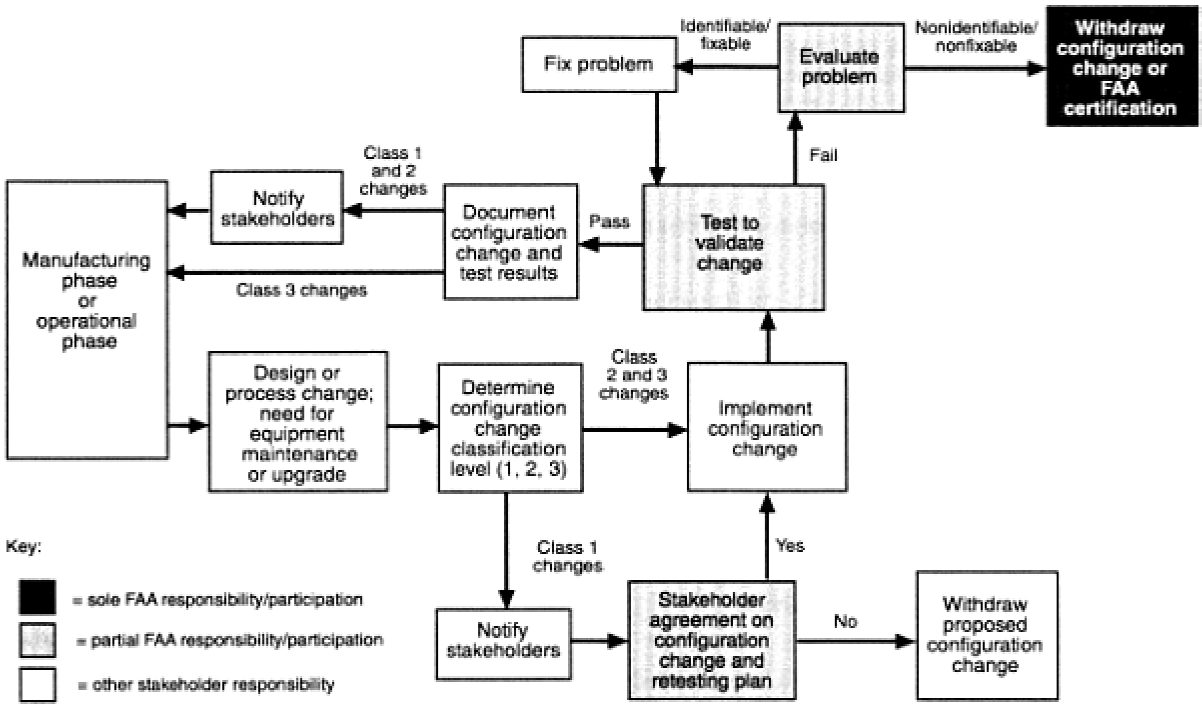


Figure 5-6
Configuration change process for an EDS during manufacture or operation.

Recommendation. Configuration-control boards such as the ones used in many industries should be established to determine which proposed changes will be implemented and the implementation and testing conditions that will be imposed.

Recommendation. The FAA should

- require explosives-detection equipment manufacturers to implement change management as a minimum requisite for certification
- develop a change classification system with stakeholder involvement
- establish a mechanism (e.g., a stakeholders configuration-control board) for stakeholder review of proposed changes (of an agreed-upon priority) to explosives-detection equipment

Although, in reality, determining the class of a change will be the responsibility of the manufacturer, review of the classification of changes (and the appropriateness of such classifications) should be included in a third-party configuration audit.

Configuration Management of Software for Explosives-Detection Equipment

Although software, hardware, and firmware form an integrated system, configuration management of software is a unique case due, in part, to the ease with which changes can be made to software code by a vendor (locally or remotely) and the relative difficulty for the user or regulator to recognize a software change. Because multiple systems are being installed at multiple locations, it is critical that software version levels be managed and controlled such that the version being executed at any one location is known. Uncontrolled modification of software in the field should not be permitted.

Similar to a hardware CI, a computer software configuration item (CSCI) is a uniquely identifiable subset of the *system* configuration. Each software module, for example, may constitute a separate CSCI. Furthermore, each CSCI should be assigned a unique identifier that relates the software to its associated software design documentation, revision, and release date.

Recommendation. The FAA should

- require manufacturers of explosives-detection equipment to select and document the baseline configuration of each CSCI prior to certification
- require manufacturers of explosives-detection equipment to uniquely identify each CSCI with a name or serial number and a version number (identifiers should be embedded in source, object, or executable file code and, when applicable, electronically embedded in firmware)
- require EDS vendors to identify software changes by labeling modified software with a unique version number that is traceable to the original certified software (e.g., modified software version 3.1 may be labeled "version 3.1 a")

As with hardware changes, proposed changes in software will require review by a body with appropriate expertise to determine the scope of regression testing[2] necessary to ensure that critical operational performance characteristics are maintained. Internally, manufacturers may choose to maintain a separate software configuration-control board to perform this function. However, when the other stakeholders are involved, the panel recommends that software and hardware experts be included in a single board that will review proposed system changes—software, firmware, and hardware alike.

Changes to the software of a particular model of explosives-detection equipment may be testable through the use of a *digital database*, analogous to a test article for the system hardware. Such a database might contain the images or other appropriate data collected during certification testing, with a record of the decision made for each bag (for which data were collected) by the baseline configuration system. Comparing the decisions made for each bag by a system with updated or modified software and using the standard input data (from the digital database) would allow determination of improvements in performance or other effects of software changes. Such data could also be used to test individual CSCIs without the necessity of physical tests of all hardware components. Ideally, it would be possible to obtain digital data from the output of the different operational subsystems. This data could then be used as a performance-verification tool for future changes in explosives-detection equipment by a specific manufacturer.

Recommendation. The FAA should develop and maintain control of a digital database that contains information collected during certification testing of explosives-detection equipment. Control of this database by the FAA in a manner similar to how they control the primary standard bag set, without release to equipment manufacturers or any other party, would provide assurance of comparability of tests performed at different times.

A test digital database similar to the digital database proposed above could be developed by testing a different bag set than the one used to develop the digital database (i.e., a bag set other than the primary standard bag set or the secondary standard bag set). This "test digital database" could then be made available to manufacturers so that they could perform software tests (e.g., precertification-type tests) at their own site. This tool would allow for an accelerated design program, both for new designs and for the modification of existing designs.

Configuration Management of Deployed Explosives-Detection Equipment

Discovery of failures, faults, or errors during operational tests or service of deployed explosives-detection equipment will often necessitate postcertification changes. Such changes can lead to "secondary" failures—faults or errors that were either not present or not detected when the system was first certified. Testing detects the presence of errors, but cannot guarantee the absence of errors. With each change, therefore, testing protocols should be re-evaluated to determine if they are capable of detecting errors that may be introduced by a change.

Often service contracts are negotiated by the end user of explosives-detection equipment with a party other than the manufacturer of the equipment. This third-party service provider is an important stakeholder in the configuration-management and performance-verification process.

Recommendation. The FAA should require the party responsible for postdeployment maintenance (e.g., third-party service providers) of explosives-detection equipment to apply configuration control to explosives-detection equipment in airports.

Expertise Required and Software Tools Available for Configuration Management

It is likely that configuration-management experience and procedures will vary from manufacturer to manufacturer and within the FAA. As a whole, the industry for explosives-detection equipment is relatively young, and the level of configuration-management expertise tends to correlate directly with the maturity of the manufacturer. The FAA and the manufacturers should, at a minimum, maintain a level of configuration-management expertise that allows them to

[2] *Regression testing* is the process of validating modified parts of a software program and ensuring that no new errors are introduced into a previously tested code. Although software may have been tested during its development, program changes during maintenance require that parts of the software be tested by a regression test.

interpret and apply the fundamental principles of baseline management and change management. For example, the FAA and the manufacturers should be able to identify appropriate CIs and establish a baseline configuration for test items and explosives-detection equipment, respectively.

Recommendation. The FAA and EDS manufacturers should maintain expertise to fully implement the following configuration-management concepts:

- configuration item identification
- configuration-control and change management
- configuration status accounting
- configuration auditing

There are several commercially available software-based configuration-management tools that are applied in technology-intensive industries. The panel believes that the use of software-based configuration-management tools would facilitate tracking changes to the configuration of a CI, a CSCI, or a system baseline. Existing commercially available configuration-management tools can meet the needs of all explosives-detection equipment stakeholders, including equipment manufacturers, airlines/airports, and the FAA. However, software-based configuration-management tools developed internally by manufacturers may also be appropriate—if they enable version control.

Recommendation. The FAA and the manufacturers of explosives-detection equipment should implement and maintain expertise in software-based configuration-management tools as a part of their management plan.

PERFORMANCE VERIFICATION

The FAA has defined and prioritized the threats to aviation security and has defined an operational test protocol for radiographic x-ray scanners (used for screening carry-on baggage) and passenger-screening metal-detecting portals. However, they have not developed performance requirements that are testable in airports or at manufacturing sites or adopted an airport performance-verification protocol for automated explosives-detection equipment. Developing such performance requirements and test protocols would allow for clear communication between the FAA and the manufacturers and end users. The test plan outlined in a 1993 National Research Council report (NRC, 1993) could serve as a model for a test protocol appropriate for use in an airport or at a manufacturing site. Such a protocol should include

- definition of the baseline configuration and management approach of the test
- definition of the test conditions and requirements including test objects (e.g., simulated explosives), support equipment, test personnel, and test procedures
- configuration management of the test protocol, including test objects, collected data, test requirements, and documentation
- determination of test duration and frequency
- determination of funding requirements

Recommendation. The FAA should require a wide variety of tests for maintaining EDS certification, including qualification testing and periodic verification testing of detection performance levels (using a secondary standard bag set), frequent monitoring of critical system parameters (using test articles), and continuous self-diagnosis of subsystem parameters (e.g., voltages and currents) to detect incipient problems.

In the sections that follow, a protocol is discussed to provide guidelines for developing performance-verification procedures for certified and noncertified explosives-detection equipment.

Explosives-Detection Equipment Architecture and Performance Verification

Certification testing determines the integrated performance of all of the operational subsystems of equipment under examination. During certification, explosives-detection equipment is tested as a monolithic entity—without testing individual components. The panel believes that this mode of testing results in a limited amount of information regarding how modifications to operational subsystems and components could affect the performance of the explosives-detection equipment. Testing of appropriate parameters, however, could provide such information. Early identification of operational subsystems will increase the efficiency and rigor of performance verification, particularly with respect to factory testing. For x-ray CT-based equipment, examples of operational subsystems include the illuminator— that is, the x-ray generator composed of a high-voltage generator and an x-ray source—and the detector, which measures the modulation in the x-ray profile exiting the scanned bag. The relationship between component parameter values and the performance of operational subsystems, and, ultimately, overall detection performance must be known for such tests to be effective.

Test Objects for Testing Bulk Explosives-Detection Systems

Test objects are a variety of objects used to test the performance of explosives-detection equipment. These objects range from test articles that measure a critical system parameter (an example is described in Appendix F), to materials that simulate explosives, to the primary standard bag set— which contains explosives—to determine the detection performance of explosives-detection equipment (Table 5-1). The ability to test with a simulated explosive (i.e., as a part of a secondary standard bag set) is critical to the bulk explosives-detection equipment development and manufacturing process, as well as to field testing. However, the nature of a simulated explosive is dependent on the explosive material it is intended to simulate, as well as the technology that will be used to detect it.

TABLE 5-1 Types and Purposes of Test Objects

Test Objects	Definition	Purpose
Primary standard bag set	Representative passenger bags, some containing explosives at threat quantity	Simulate threat
Secondary standard bag set	Representative passenger bags, some containing simulants representing explosives at threat quantity	Simulate primary standard bag set (requires no special safety-related handling permits or precautions)
Test articles	Individual articles, including items such as simulants, the InVision IQ simulants test bag, and ASTM (1993) standardized step wedges and CT phantoms	Elicit a predetermined response to test critical system parameters

Currently, only explosives are used during certification testing of explosives-detection equipment, and the availability of FAA-validated secondary standards is limited. The FAA certification process, however, provides an ideal opportunity to correlate, for a particular piece of explosives-detection equipment, technical test data using explosives with that obtained using secondary standards. Furthermore, it is the opinion of the panel that the FAA has the responsibility for and should continue to work toward ensuring the availability of appropriate secondary standard materials.

Prior to FAA validation of secondary standard materials developed by equipment manufacturers, the FAA should require manufacturer validation of such materials as discussed in paragraph 2.4.5 on page 17 of the *Management Plan for Explosives Detection System Certification Testing* (FAA, 1993). Furthermore, the FAA should validate or arrange for independent validation of all simulants (regardless of who developed them) to be used for qualification testing and verification testing according to the guidelines presented in Annex II of *Detection of Explosives for Commercial Aviation Security* (NRC, 1993).

Recommendation. For qualification and verification testing, the FAA should work with EDS manufacturers and users to develop a secondary standard bag set for each specific technology or technology class.

Recommendation. The FAA should

- continue to support the development and validation of test objects, simulated explosives, and associated test articles
- continue to work with the International Civil Aviation Organization on the development of simulated explosives and other test objects to encourage development of internationally recognized standards
- develop a secondary standard test article with each manufacturer that will meet the FAA's and the end user's needs for daily testing of explosives-detection equipment in airports
- develop a secondary standard bag set that consists of a number of representative international passenger bags that do not contain threat objects and a number of bags containing simulated explosives at an amount that represents a threat quantity of explosives (the simulated explosives should mimic the threats in the primary standard bag set used for certification and that have been validated for the explosives-detection technology)

Recommendation. The secondary standard bag set should be developed, retained, and controlled by the FAA personnel responsible for the conduct of the certification test and evaluation and utilized in the conduct of periodic verification testing.

Recommendation. The secondary standard bag set should be controlled to assure reliable test results, as is done by the FAA for the primary standard bag set. It is important that the FAA periodically (on the order of the lifetime of the simulants) verify the condition, configuration, and performance of the secondary standard bag set.

All data generated by the use of the secondary standard bag set should be collected, analyzed, reported, and maintained by the FAA. A proposed test protocol based on the secondary standard bag set is presented in Appendix F.

The performance of explosives-detection equipment may be inferred by testing critical system parameters using a test article or by continuously monitoring subsystem parameters (Table 4-1). A critical system parameter is a parameter that is fundamental to the performance of explosives-detection equipment. Such a parameter is directly related to the ability of explosives-detection equipment to detect an explosive. For the case of a CT-based imaging system, these parameters include the macrosystem transfer function, spatial resolution, and background noise. Test articles exist to test critical system parameters for many explosives-detection technologies as a result of their use in other applications— for example, CT in the medical field.

In addition to the critical system parameters, there are subsystem parameters, which are measurable parameters that indicate the operational consistency of explosives-detection equipment (e.g., voltage and current measurements). There is a rich history in the medical imaging community of testing subsystem parameters associated with specific components of medical CT systems. Most manufacturers perform tests associated with the x-ray generator (or, referring to our defined explosives-detection equipment anatomy, the illuminator) that determines the accuracy of the x-ray tube potential and the x-ray tube current. Inappropriate calibration of these two subsystem parameters can cause errors in the output of the complete CT system, particularly with respect to any quantitative determination of the x-ray attenuation coefficient, a critical system parameter used to characterize the objects being imaged Testing, monitoring, and evaluating the accuracy of the x-ray tube potential and the x-ray tube current is as important in CT-based explosives-detection equipment as it is in a medical CT system. Tests on other subsystem parameters, such as voltage and noise levels associated with the x-ray detector—a separate component from the illuminator—are also incorporated in most factory test programs for medical CT systems and, therefore, could also be considered for CT-based explosives-detection equipment.

Recommendation. For monitoring the performance of EDSs, the FAA should work with manufacturers to develop a set of critical system parameters (and their tolerances) that could be monitored frequently and recorded to track changes in performance during normal operations or to verify performance after maintenance or upgrading.

Critical system parameters (e.g., attenuation coefficient) are measurable with appropriately designed test articles that need not include simulated explosives (Table 5-1). Subsystem parameters (e.g., voltages) can be monitored continuously and do not necessarily require the use of a test article.

Certification testing determines the integrated performance of all operational subsystems of explosives-detection equipment. During certification, explosives-detection equipment is tested as a monolithic entity without testing individual subsystems or components. The panel concluded that this mode of testing results in a limited amount of information regarding how modifications to operational subsystems and components could affect the performance of the explosives-detection equipment. Testing of appropriate parameters, however, can provide such information.

Recommendation, The FAA should verify critical system parameters during certification testing.

Recommendation. The FAA should

- request that manufacturers of explosives-detection equipment identify critical system parameters that are directly related to the ability of such equipment to detect explosives (e.g., macrosystem transfer function in CT-based equipment) and provide for monitoring and reporting of these parameters at appropriate intervals
- request that manufacturers of explosives-detection equipment explicitly define appropriate subsystems consistent with the panel's taxonomy for sampling, analyzing, classifying, and interfacing
- request that manufacturers of explosives-detection equipment identify appropriate test parameters (including tolerances) for the subsystems or components on which subsystems depend (e.g., voltage or current levels)
- measure and record critical system parameter and subsystem test parameter values during certification testing to determine baseline test parameter values
- establish critical test parameter and subsystem test parameter value ranges, based on certified baseline test parameter values, that may be used as an indication that the overall system meets certified performance (parameter values measured in the field could be referenced against the established parameter value ranges to infer performance)

Note that validation of critical and subsystem parameter ranges may require monitoring the correlation of these ranges with equipment performance over time—even after deployment. In this context, system performance pertains to the ability of the equipment to detect the explosive compositions and configurations (e.g., sheet and nonsheet bulk explosives) defined by the FAA's certification criteria. Therefore, parameter values measured outside of accepted ranges should trigger testing the equipment with the secondary standard bag set in the field. Figure 5-7 illustrates a verification testing process.

Performance Verification of Bulk Explosives-Detection Systems

The FAA needs qualification testing, verification testing, and monitoring protocols to verify the performance of deployed EDSs, because it is not reasonable to duplicate certification testing in airports and manufacturing sites, and there is a need for determining that an EDS is operating properly on a daily basis. The first step in the development of a qualification, verification, and monitoring testing protocol to verify the performance of deployed bulk explosives-detection equipment is the realization that performance requirements cannot easily be directly related to the FAA certification standard (e.g., explosives cannot be easily handled in airports), but must instead be governed by what is practical to handle at manufacturing sites and in airports. To accomplish this, the FAA must first define a primary standard (e.g., a set of suitcases containing bombs) from which to reference a more practical test item. For example, the bag set used for certification testing of an EDS may serve as this primary standard. Given the assumption that the primary standard bag set accurately reflects the "real threat," there is a level of uncertainty (or risk) involved in modeling the primary standard bag set with a secondary standard bag set (e.g., a simulated explosive in a test suitcase). The next logical step, testing critical parameters (e.g., resolution) with test articles that are intended to correlate to system performance, also brings into question how realistically the test object reflects the real threat. Continuous monitoring of appropriate subsystem parameters (e.g., x-ray tube current) can provide evidence of changes in system performance that may indicate changes in detection and false-alarm rates.

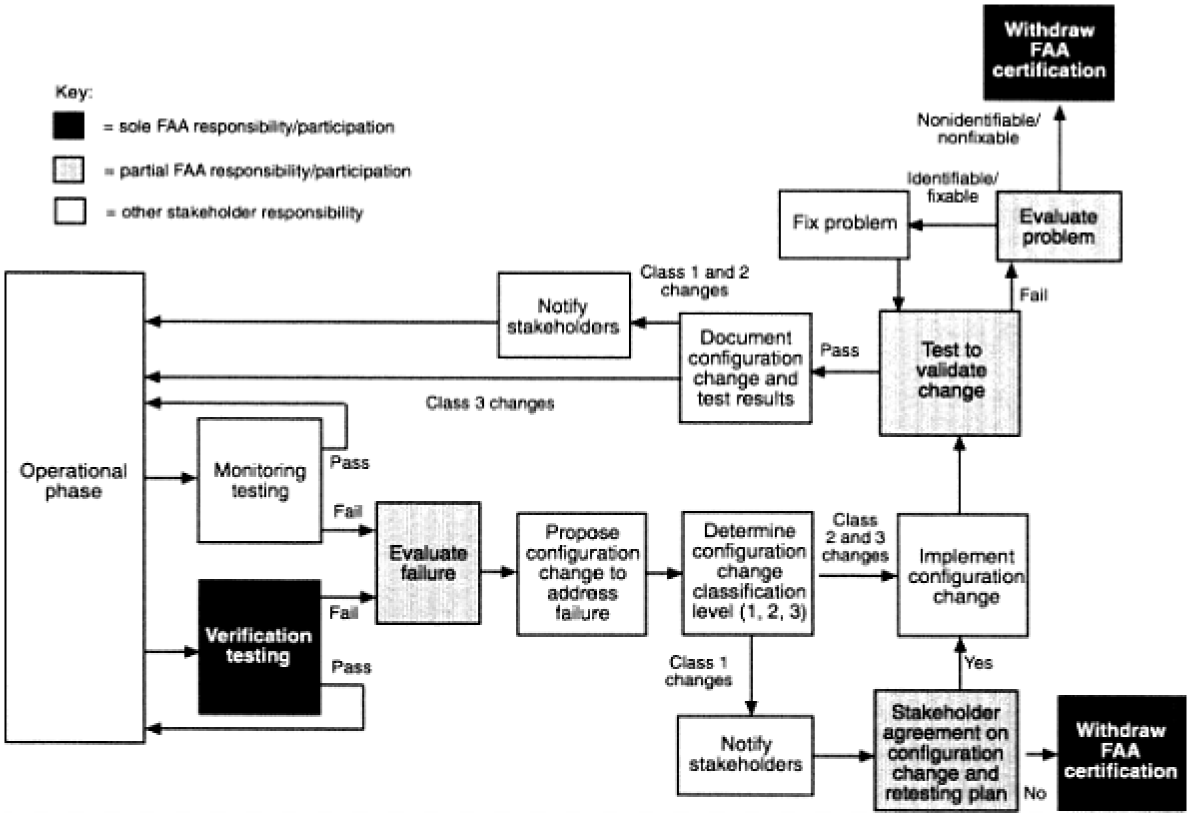


Figure 5-7
Monitoring and verification testing for certification maintenance.

As described in Figure 5-8, the further removed a test method is from the real threat, the greater the uncertainty about the ability of the test method to effectively measure the performance of the EDS. The practicality of conducting performance verification, however, increases concurrently with degree of uncertainty. In the context of performance verification, practicality reflects test duration and difficulty and the likelihood that the test will not disrupt airport and airline operations. That is, the less obtrusive the performance-verification test, the more practical it is. Furthermore, Figure 5-8 indicates the dependence of each successive level of performance verification on the previous level. For example, the quality of the primary standard bag set, and analogously the secondary standard bag set, is dependent on the understanding of the real threat. Similarly, the efficacy of testing a critical parameter with a test article is dependent on the secondary standard bag set to resolve a potential problem detected by such a test.

In this light, it is apparent that the FAA needs to develop a performance-verification protocol for airport testing of an EDS that incorporates more than one level of testing. For example, daily diagnostic testing of critical parameters of an EDS could be augmented by monthly testing with simulated explosives hidden in luggage or an annual check with explosives. Regardless of the performance-verification protocol established, external developments such as emerging explosives-detection technologies and changing threats to aviation security should be reflected with appropriate changes to primary standards, secondary standards, and diagnostic tests.

Recommendation. The FAA should design and validate a two-tiered protocol for performance-verification testing of bulk EDSs:

1. Using a test article (e.g., a simulated explosive, step wedge, etc.) during certification testing, establish acceptable ranges of the critical system parameter values deemed critical to the alarm/no alarm output of a certified EDS. This test can then be repeated in the airport or at the manufacturing site to determine if the deployed or to-be-deployed certified EDS has parameter values within the acceptable limits. In addition, subsystem parameter values can be continuously monitored to assure the operational consistency of the EDS.
2. Using a secondary standard bag set, obtain estimates of the probability of detection (P_D) and the probability

of false alarm (P_{FA}) to be used in addition to the P_D and P_{FA} values determined using the primary standard bag set during certification testing. If airport test results (e.g., P_D and P_{FA} of the deployed EDS) and results from tests performed at the FAA (e.g., P_D and P_{FA} of the EDS that underwent certification testing) using the same secondary standard bag set show statistically significant agreement, the performance of the deployed EDS could be said to be verified. The FAA could use the protocol presented in Appendix A of *Detection of Explosives for Commercial Aviation Security* as a model for developing a performance-verification protocol suitable for use in airports or at manufacturing sites.

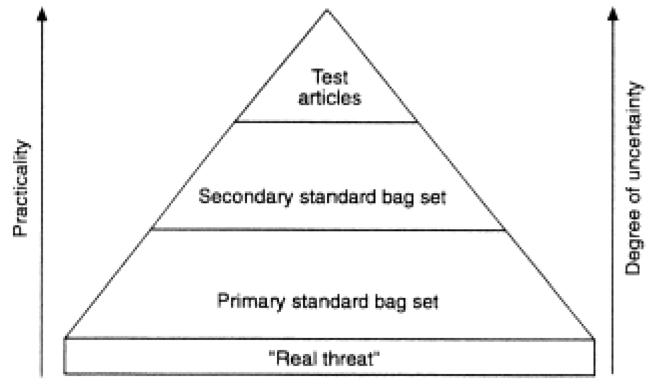


Figure 5-8 Schematic representation of the relationship between various levels of performance verification test objects and the "real threat" and the relative practicality and degree of uncertainty associated with them.

The first option would be useful for daily calibration and diagnostic testing of an EDS. This approach, however, will only provide inferential information regarding the capacity of the EDS capacity for detecting explosives. The adequacy of this information for predicting detection performance depends on the proper choice and understanding of the critical parameters measured. This type of testing will not provide a quantitative measure of performance relative to certification criterion (i.e., it does not estimate P_D and P_{FA}) but could indicate small changes in system behavior, which may give early warning about changes in detection performance. Therefore, the panel recommends that the second, more rigorous, approach be utilized periodically to yield performance probabilities (P_D and P_{FA}) to correlate performance-verification testing more directly with certification specifications.[3] An example test protocol for each approach is given in Appendix F.

In addition to monitoring the detection performance of an EDS, it is important to monitor the false-alarm rate and the baggage throughput rate of the system. These quantities can be monitored continuously as passenger baggage passes through the system. However, if the false-alarm rate is determined in this manner to be unacceptably high, the system should not be taken off-line. Rather, this situation warrants testing the system with the secondary standard bag set to determine if the false-alarm rate is within specifications. If the system is found—with the secondary standard bag set— to have a false-alarm rate that is outside of specifications, the FAA, the user, and the manufacturer should develop a plan to correct this problem. Similarly, if the baggage throughput rate drops to a rate that is unacceptably low, the FAA, the user, and the manufacturer should develop a plan to correct this problem.

Performance Verification of Noncertified Explosives-Detection Equipment

Noncertified explosives-detection equipment comprise bulk explosives-detection equipment that have not met FAA certification requirements and trace detection devices, for which there are no FAA-defined certification criterion. As a result of the Federal Aviation Reauthorization Act of 1996 (Public Law 104-264), noncertified explosives-detection equipment has been, and will continue to be, deployed by the FAA in U.S. airports. The panel believes that the FAA has the responsibility for determining the performance capabilities of all equipment deployed as per Public Law 104-264 and for establishing a plan for maintaining the determined level of performance in the field.

Bulk Explosives-Detection Equipment

To date, the FAA has not established formal performance specifications for noncertified explosives-detection equipment. The FAA has, however, developed a baseline test that is used to determine what noncertified bulk explosives-detection equipment will be deployed (FAA, 1995). The FAA tests explosives-detection equipment against the same categories and amounts of explosives that are used in certification testing (as well as amounts greater than and less than those used during certification testing) to determine a performance baseline for that equipment. A field test protocol for the deployed explosives-detection equipment may involve simulants for each of the categories in a secondary standard bag set, where the expectation would be that the average P_D and P_{FA} would be similar to that when explosives were used.

Recommendation. For bulk noncertified systems and devices, the panel recommends that

[3] Note that the bags that compose the primary and secondary standard bag sets will not necessarily be representative of those being processed at any one airport. It is likely that the daily P_{FA} for actual passenger baggage at a particular airport will vary from that determined using the secondary standard bag set. Therefore, the daily P_{FA} should not be used for comparison against certification requirements for the purpose of disqualifying a deployed system from service.

- the FAA require the manufacturers to submit one copy of each noncertified model that has been, or is going to be, deployed to certification testing so as to obtain a measure of the baseline performance against certification criteria
- the test protocol described above for bulk EDSs be used, with the exception that performance specifications would be based on the baseline performance determined for each type of noncertified system or device rather than on certification requirements

Trace Detection Devices

The FAA's protocol for evaluating trace explosives-detection devices uses extremely small amounts (of known quantity) of each category of explosives on a variety of substrates, with some substrates intentionally left uncontaminated. Several trace explosives-detection devices were shown by the FAA to be capable of finding explosive materials on the surface of various types of carry-on luggage. These tests, however, do not distinguish between the capabilities of the machine and the ability of the operator to locate and adequately sample the contaminated surface.

In contrast to bulk detection methods, trace detection systems are more likely to suffer from false negatives (i.e., an explosive-containing bag is not detected) due to inadequate sample collection, than false positives (i.e., false alarms) triggered by nonexplosive items. Furthermore, for trace detection devices sample collection is operator dependent to the point that the performance of a trace device is directly dependent on the performance of the human operator.

The panel determined that a performance-verification testing protocol for trace explosives-detection devices should test each of the following three tasks:

- *sample collection*: determine if, during normal operation, the operators adequately sample simulated carry-on luggage that (unknown to the operators) has known amounts of explosive placed on baggage handles, zippers, and other areas that would likely be contaminated if the baggage contained an explosive
- *sample transfer*: determine the efficiency with which the sample collection techniques transfer the material for detection from a surface known to be contaminated with a known amount of explosive
- *sample analysis*: determine if the trace detection device adequately maintains the required detection limit while functioning continuously

QUALITY SYSTEMS AND STANDARDS

In the preceding discussions, specific recommendations were made regarding performance verification and configuration management. However, performance verification and configuration management are elements of a broader quality system. A quality system structure should be put in place for oversight, validation, verification, and management of configuration management and performance-verification activities throughout the life cycle of explosives-detection equipment.

Recommendation. Every stakeholder must have a quality system in place that includes oversight, validation, verification, and procedures for configuration management and performance verification covering that stakeholder's responsibilities throughout the life cycle of an EDS.

Recommendation. Each stakeholder must have a documented and auditable quality system that governs its specific responsibilities in the manufacture, deployment, operation, maintenance, and upgrading of EDSs.

To provide effective aviation security, each of the stakeholders should have a quality system in place. As the regulator of U.S. commercial aviation, the FAA should define quality system requirements that are compatible with stakeholder needs. For example, the manufacturers of explosives-detection equipment need a quality system that deters unintentional performance degradation changes without stifling innovative product improvements. Air carriers, airports, and other end users need a quality system that ensures that baggage-handling facilities operate smoothly and that proper detection performance could be demonstrated as requested by the FAA. In addition to ensuring confidence in its testing protocols, procedures, data handling, and test objects, the FAA must have its own quality system. All of the quality standards considered by the panel could provide the framework for development of quality systems that meet individual stakeholders needs.

Recommendation. Because there is already a global movement toward using the ISO 9000 series of quality system standards, the FAA should base both its in-house quality system and its requirements for other quality systems on these standards. The FAA should accept the quality system of any stakeholder that has the following attributes:

- a definition of the critical parameters, procedures, and processes to be monitored
- documented evidence of an internal quality system
- a definition of the methods for controlling and verifying changes to procedures and processes
- a definition of an internal audit program
- provision for third-party auditing of conformance with the quality system

The FAA would benefit from applying the principles of ISO 9000 to its Aviation Security Program. For example, the FAA's internal quality system could track the FAA's conformance to its *Management Plan for Explosives Detection System Certification Testing* (FAA, 1993), its *Technical Center Baggage Inspection System: Airport Operational Demonstration Project Test and Evaluation Master Plan* (FAA, 1995), or the manufacturing management plan recommended in this report. It is the opinion of the panel that diligent adherence by the FAA to an auditable quality system (e.g., ISO 9000) would significantly improve the integrity of deployed explosives-detection equipment. Finally, an auditable quality system would provide a mechanism to determine the FAA's conformance to its own management and test and evaluation plans.

Recommendation. The FAA should implement and document its own quality system under which precertification activities, certification testing, test standards development and maintenance, and testing for maintaining certification are conducted.

Recommendation. The FAA should

- define and record its critical test and evaluation procedures, equipment performance requirements, and data-handling procedures
- monitor its requirements and procedures by its quality system
- identify in their quality plan all objects (e.g., secondary standard bag set), including hardware, software, and firmware, that are critical to conducting certification, approval, or qualification, or verification testing of explosives-detection equipment
- receive an audit of their quality system—including (where applicable) a configuration audit—from an independent third-party auditor

For a quality system to be effective in a manufacturing environment, the critical manufacturing steps must be defined. An ISO 9001 audit, for example, will verify that a manufacturer is following their quality system, but does not validate that the quality system results in the production of a certifiable EDS.

Recommendation. The FAA should

- require that equipment manufacturers utilize a quality system consistent with the requirements for ISO 9001
- require that equipment manufacturers define critical manufacturing parameters, procedures, and processes that will be monitored by the manufacturers' quality system
- require equipment manufacturers to identify critical manufacturing steps, components, and software modules as part of their quality planning process
- require explosives-detection equipment manufacturers to provide documented evidence of their internal quality system prior to certification testing
- provide guidelines for, and requirements of, a quality system to potential applicants for certification of explosives-detection equipment

Recommendation. The FAA should ensure that each stake-holder periodically receive an audit of their quality system— including (where applicable) a configuration audit—from an independent third-party auditor.

The previous discussion was focused on quality systems for the FAA and for manufacturers of certified EDSs. However, the FAA also purchases noncertified equipment for airport demonstrations and operational testing. As purchaser, the FAA should require that the manufacturers of non-certified equipment have in place a quality system that meets the same standards as the quality systems for manufacturers of certified equipment.

Recommendation. The FAA should require that the manufacturers of noncertified equipment demonstrate the same level of quality system covering both manufacturing and upgrade as required for manufacturers of EDSs when noncertified equipment is purchased by the FAA for airport demonstrations, operational testing, or airport deployment.

Recommendation. The FAA should ensure that the manufacturers of noncertified explosives-detection equipment purchased by the FAA periodically receive an audit of their quality system including a configuration audit—from an independent third-party auditor.

Recommendation. The FAA should ensure that airlines, other end users, and organizations responsible for maintenance and upgrades (e.g., manufacturers or third-party service providers) demonstrate a quality system that covers the operation, maintenance, and upgrade of noncertified EDSs that are purchased by the FAA for airport demonstrations, operational testing, or airport deployment. Such a quality system should meet the FAA's requirements of quality systems used by operators and maintainers of certified explosives-detection equipment.

Once deployed, explosives-detection equipment becomes an essential part of an air carrier's baggage-handling system. Air carriers utilize quality control and maintenance procedures to ensure that baggage gets to the proper airplane on time and free from damage. Incorporating explosives-detection equipment into the baggage-handling system adds a critical function to the intent of baggage handling, that is, delivering baggage to the proper airplane free from explosive threats. Proper operation, testing, and maintenance of explosives-detection equipment is crucial to its effectiveness, and therefore the principles of ISO 9002 should be followed to maintain operational, testing, and maintenance procedures.

Recommendation. The FAA should

- require that air carriers (or other end users) utilize a quality system that is consistent with the requirements for ISO 9002
- define, in partnership with the air carriers and equipment manufacturers, critical operating, testing, and maintenance procedures that should be monitored by the air carriers quality system
- require air carriers to provide documented evidence of their internal quality system that supports their aviation security effort

- provide its guidelines for, and requirements of, a quality system to the air carriers or other entities responsible for operation, testing, and maintenance of explosives-detection equipment

PRECERTIFICATION REQUIREMENTS

Modifications to explosives-detection equipment during the two-to-three week certification testing period can be time-consuming and costly. Furthermore, such modifications can lead to unforeseen problems later in the life cycle of the equipment. Therefore, the baseline configuration established prior to certification should be maintained throughout the certification process. Diligent use of the *Configuration Log*, as defined in the *Management Plan for Explosives Detection System Certification Testing* (FAA, 1993) would facilitate baseline management during certification testing. In addition, a manufacturer of explosives-detection equipment is responsible for providing quantitative evidence that a system submitted for certification is a production-representative system (not a developmental system), manufactured on "released for manufacture" documentation, and prepared for certification testing.

The panel endorses the requirement in the FAA certification criteria (FAA, 1993) specifying that quality systems should be in place prior to certification testing for each subsequent life-cycle phase of an EDS. Because each stakeholder has different responsibilities during each life-cycle phase, the quality systems may vary. But they must all have the attributes specified in the previous recommendation. Although individual stakeholder activities may already be under the control of quality systems, the panel believes that it is critically important to have comprehensive quality systems that cover all life-cycle phases of an EDS. Furthermore, it is important that each stakeholder periodically receive a third-party audit of their quality system, including, where applicable, a configuration audit.

Recommendation. Explosives-detection equipment presented to the FAA for certification testing must be the product of an implemented and documented manufacturing quality system. Subsequent units must be manufactured according to the same quality system to maintain certification.

The panel concurs with the FAA's Vendor Instructions and Data Qualification Requirements (Section II, FAA, 1993), which must be followed and submitted to begin the process of certification of explosives-detection equipment. The panel, however, is of the opinion that the Test Plan (Paragraph 2.4.2, FAA, 1993) should include additional requirements. For example, a formal precertification test, conducted by the manufacturer on candidate production-representative equipment, would determine that the equipment is likely to meet FAA certification criteria. This process would include a review (by the FAA) of the results of a formal pre-certification test to determine if the system is ready to be submitted for certification testing at the FAA Technical Center (see DOD, 1995).

Recommendation. The FAA should adhere to the requirement that the manufacturers conduct, and provide documentation of, precertification testing of explosives-detection equipment they have deemed to be production representative.

The formal precertification test provides quantitative evidence that the system meets (or fails to meet) the FAA's performance requirements prior to certification testing. During the formal precertification test, errors, faults, and failures may be encountered. Problems detected in the equipment or individual subsystems during the test are sorted by priority and documented as Priority 1 (critical), Priority 2 (crucial), Priority 3 (essential), or Priority 4 (nonessential), as shown in Table 5-2. The panel concluded that manufacturers should be required to enact, and provide documentation of, remediation actions to problems detected during the formal precertification test prior to submitting the explosives-

TABLE 5-2 Criteria for Classifying Problems with Explosives-Detection Equipment

Classification	Criteria
Priority 1 (critical)	Any failure condition or design error that would (1) prevent the accomplishment of an operational or mission-essential capability (e.g., detecting explosives) specified in baseline requirements, (2) prevent the operator's accomplishment of an operational or mission-essential capability, or (3) jeopardize personnel safety.
Priority 2 (crucial)	Failure conditions or design errors, for which no alternative work-around solution is known, that would adversely affect (1) the accomplishment of an operational or mission-essential capability specified by baseline requirements so as to degrade performance, or (2) the operator's accomplishment of an operational or mission-essential capability specified by baseline requirements so as to degrade performance.
Priority 3 (essential)	Failure conditions or design errors, for which an alternative work-around solution is known, that would adversely affect (1) the accomplishment of an operational or mission-essential capability specified by baseline requirements so as to degrade performance, or (2) the operator's accomplishment of an operational or mission-essential capability specified by baseline requirements so as to degrade performance.
Priority 4 (nonessential)	Failures or design errors that could not affect required operational or mission-essential capability and are an inconvenience to the operator.

Sources: Radio Technical Commission for Aeronautics (1992) and DOD (1994).

detection equipment for certification testing. When software problems are detected during precertification testing they should be corrected with completely compiled software code as opposed to software patches.[4]

Recommendation. The FAA should follow the guidelines listed below in developing requirements for problem remediation:

- *Priority 1 or 2 problems*: Mandate that all changes to remedy system failures and design errors have been implemented and appropriately retested. Priority 1 or 2 problems should not be corrected by software patches, but should possess completely compiled software code. Priority 1 or 2 problems should not be corrected with hardware patches.
- *Priority 3 or 4 problems*: For problems classified as Priority 3 or 4, the FAA may allow manufacturers to proceed with certification without correcting the problems and retesting the equipment provided that uncorrected problems and problems corrected by software patches are specifically identified as part of the certification process. Patches may be made but are not encouraged. A limited number of patches may be necessary due to preproduction hardware configurations that impact system performance without functionally limiting it. The FAA should, however, strongly encourage manufacturers to submit equipment that possess a completely compiled software code.

If, during certification testing, the FAA determines that any of the appropriate precertification requirements have not been met—for example, if Priority 1 or 2 problems are encountered—the certification process should be stopped immediately. Certification testing should not be resumed until the manufacturer corrects any Priority 1 or 2 shortfalls, reestablishes a baseline configuration, and re-attests to the system's readiness for certification. The FAA may also stop dedicated certification testing if the number of Priority 3 problems encountered is sufficient to significantly impact the integrity of the test or the FAA's ability to continue testing.

[4] A software patch is a software modification in which a binary code is inserted into executable files without recompiling from the source program. The use of patches is not considered acceptable software engineering practice, although there are situations in which there are no other options (Buckley, 1993).

References

AAPM (American Association of Physicists in Medicine). 1993. Specification and Acceptance Testing of Computed Tomography Scanners. Report No. 39 . College Park, Md.: American Institute of Physics.
ASTM (American Society for Testing and Materials). 1993. Design and Use of Ionizing Radiation Equipment for the Detection of Items Prohibited in Controlled Access Areas. F792-88. West Conshohocken, Pa.: American Society for Testing and Materials.
Blanchard, B.S. 1986. Logistics Engineering and Management, 3rd ed. Englewood Cliffs, N.J.: Prentice-Hall.
Buckley, F.J. 1993. Implementing Configuration Management: Hardware, Software, and Firmware. Piscataway, N.J.: IEEE Press.
Burrows, C., S. Dart, and G.W. George. 1996. Ovum Evaluates Configuration Management Tools. London, U.K.: Ovum Press.
DOD (U.S. Department of Defense). 1963. Quality Program Requirements. MIL-Q-9858A. Washington D.C.: U.S. Department of Defense.
DOD. 1994. Software Development and Documentation. MIL-STD-498. Washington, D.C.: U.S. Department of Defense.
DOD. 1995. Configuration Management. MIL-STD-973. Washington, D.C.: U.S. Department of Defense.
FAA (Federal Aviation Administration). 1993. Management Plan for Explosives Detection System Certification Testing. Washington, D.C.: Federal Aviation Administration.
FAA. 1995. Technical Center Baggage Inspection System: Airport Operational Demonstration Project Test and Evaluation Master Plan. Washington, D.C.: Federal Aviation Administration.
FAA. 1996. The FAA Type Certification Process. Washington, D.C.: Federal Aviation Administration.
FAA. 1997a. Summary of Trace Testing Methodology in Support of the Security Equipment Integrated Product Team. Washington, D.C.: Federal Aviation Administration.
FAA. 1997b. Metal Detector Calibration/Certification Procedures for Course #00032. Washington, D.C.: Federal Aviation Administration.
Feigenbaum, A.V. 1983. Total Quality Control, 3rd ed. New York: McGraw-Hill.
Gray, J.E., K.G. Lisk, D.H. Haddick, J.H. Harshbarger, A. Oosterhof, and R. Schwenker. 1985. Test pattern for video displays and hard-copy cameras. Radiology 154: 519-527.
ICRU (International Commission on Radiation Units and Measurements). 1995. Medical Imaging: The Assessment of Image Quality. Report 54. Bethesda, Md.: International Commission on Radiation Units and Measurements.
ISO (International Organization for Standardization). 1994. ISO 9001, Quality Systems: Model for Quality Assurance in Design, Development, Production, Installation, and Servicing, 2nd ed. Geneva, Switzerland: International Organization for Standardization.
NATO (North Atlantic Treaty Organization). 1993a. NATO Quality Assurance Requirements for Inspection. Allied Quality Assurance Publication 130. Philadelphia, Pa.: Navy Publishing and Printing Office.
NATO. 1993b. NATO Quality Assurance Requirements for Final Inspection. Allied Quality Assurance Publication 131. Philadelphia, Pa.: Navy Publishing and Printing Office.
NRC (National Research Council). 1993. Detection of Explosives for Commercial Aviation Security. National Materials Advisory Board. Washington, D.C.: National Academy Press.
NRC. 1996. Airline Passenger Security Screening: New Technologies and Implementation Issues. National Materials Advisory Board. Washington, D.C.: National Academy Press.
OTA (Office of Technology Assessment, U.S. Congress). 1991. Technology against Terrorism: The Federal Effort. Washington, D.C.: Office of Technology Assessment.
OTA. 1992. Technology against Terrorism: Structuring Security. Washington, D.C.: Office of Technology Assessment.
President's Commission on Aviation Security and Terrorism. 1990. Report to the President, May 15. Washington, D.C.
Radio Technical Commission for Aeronautics. 1992. Software Considerations in Airborne Systems and Equipment Certification. Washington, D.C.: Radio Technical Commission for Aeronautics.
White House Commission on Aviation Safety and Security. 1996. Initial Report to the President, September 9. Washington, D.C.: Available on the internet: http://www.aviationcommission.dot.gov
White House Commission on Aviation Safety and Security. 1997. Final Report to the President, February 12. Washington, D.C. Available on the internet: http://www.aviationcommission.dot.gov

Appendices

Appendix A

Explosives-Detection Technologies

X-Ray Technology

Many of the explosives-detection technologies that are based on x-ray techniques measure the x-ray attenuation of the materials that make up the baggage. Because x-rays interact primarily with electrons, the x-ray attenuation coefficient is strongly correlated with the electron density of the material under investigation. The x-ray attenuation of a particular material will also depend on the energy of the x-rays being used.

The mechanisms primarily responsible for x-ray attenuation in materials at the energy ranges typically used by explosives-detection equipment are Compton scattering and the photoelectric effect. The photoelectric effect results in x-ray absorption, whereas Compton scattering merely scatters x-rays, potentially altering the path and energy of the scattered photons. The significance of the photoelectric effect is greater for materials composed of elements with a high atomic number (z), such as metals or other inorganic materials. However, this significance drops off rapidly with increasing x-ray energy. For organic materials (low z), Compton scattering is the dominant x-ray attenuation process, and it varies less with x-ray energy. Comparing attenuation measurements at different x-ray energies will therefore allow for distinguishing materials from one another. For example, inorganic materials can be identified by rapidly changing x-ray attenuation with changing x-ray energy, whereas organic materials will display a more subtle change.

Multienergy x-ray-based detection equipment have been developed and are suitable for distinguishing organic and inorganic materials and for semiquantitative density measurements. Combining the measurement of transmission and backscatter x-rays will further improve the detection of light (low z) elements as they are found in explosives; however, it will not uniquely identify explosives.

The x-ray-based systems described above will provide electron density and therefore mass density information but very limited spatial or geometric information. The x-ray radiograph or projection image is a collection of x-ray attenuation line integrals in two dimensions, but it will not be able to resolve the third dimension along the incident x-ray direction.

Computed tomography (CT) adds the capability to visually display the physical appearance of the materials in question from all three dimensions. The ability to reconstruct two-dimensional cross-sectional images (tomographs) and then full three-dimensional volumes can greatly improve the ability to determine explosive threats by identifying certain shapes or patterns, such as wires, batteries, or detonators, as well as measure the volume of the material in question. The additional geometrical information supplements the material x-ray attenuation information and results in a more specific discrimination of explosive materials. Dual-energy CT is capable of providing geometrical information as well as information pertaining to both the physical density and the effective atomic number of a material. The effective atomic number is not enough to uniquely characterize a material but provides discrimination capability over and above physical density alone.

Other x-ray-based methods utilizing high-energy photons have been discussed in the literature (Hussein, 1992; Gozani, 1988). They require x-ray energies between 10 and 30 MeV. Due to low-reaction cross sections, they also require high x-ray flux rates produced by powerful accelerators that may not be suitable for airport use. Those high-energy techniques are based on photon interactions with the nuclear properties of nitrogen, carbon, and oxygen. They provide definitive detection of the amount of material with some spatial information, but due to the small-reaction cross sections it is difficult to distinguish between the three elements.

Neutron Technology

Four basic techniques utilizing neutrons are being proposed for explosives-detection equipment (Hussein, 1992; Gozani, 1988; Barfoot et al., 1981; Overley, 1987; Hussein et al., 1990): (1) fast neutron activation, (2) thermal neutron activation, (3) fast neutron transmission, and (4) neutron elastic scattering.

The first two activation methods use the nuclear reaction of the neutron with the nuclei of nitrogen, carbon, and oxygen, which produces gamma rays at specific energies. By detecting and identifying the energy of these gamma rays, one can then determine the amount of those elements in the probe material. Using single-photon imaging techniques similar to medical applications, one can then generate a two-dimensional image of the luggage. Neutron sources can be reactors (fast neutron activation), radioactive isotopes (thermal neutron activation), or neutron tubes. In all cases, other materials in the luggage, particularly metallic items, can be activated, producing relatively long-lived isotopes (on the order of a few seconds) resulting in low-intensity radiation. Fast neutron activation can be used to determine carbon, nitrogen, and hydrogen densities. However, fast neutron nitrogen lines are generally weak, and thermal neutrons can provide a better determination of nitrogen. The thermal neutron activation method is a nitrogen-only method and is not able to provide adequate spatial information, potentially leading to a high rate of false positives.

The neutron transmission and scattering methods make use of the specific material- and energy-dependent absorption and scattering cross sections of neutrons interacting with the nuclei of different elements. They can be used to determine hydrogen, carbon, nitrogen, and oxygen content in an object. Both methods allow for limited generation of tomographic images and use accelerators as the neutron source. Due to the nature of the neutron interaction with the probe nuclei, radioactive activation of some luggage content may result.

Trace Detection Technology

Trace detection technologies are based on direct chemical identification of particles of explosive material or vapors given off by explosive material. These techniques require three distinct steps to be effective: (1) sample collection, (2) sample analysis, and (3) comparison of results with standard spectra. Sample collection is accomplished by using high-volume air flow to gather vapors or dislodge particles from surfaces or by making physical contact with the subject. Sample analysis techniques employ a variety of chemical separation and detection methods including gas chromatography, chemical luminescence, and ion mobility spectrometry. These methods estimate the molecular weight, electron affinity, and various other chemical properties of the vapor or particulate matter collected (NRC, 1993, 1996). Vapor detection can also be accomplished by using dogs. Although the sensitivity of dogs to explosive vapors has not been quantified, it is generally believed that dogs are more sensitive than the best electromechanical trace detection devices available (OTA, 1992). The major advantage of vapor detection devices is their noninvasive nature and applicability to screening both passengers and baggage. However, vapor detection techniques suffer from potentially high nuisance

TABLE A-1 Mass Density and Composition of Common Explosive Materials and Selected Nonthreat Items

Material	Mass Density (Kg/m^3)	N Density (Kg/m^3)	H Density (Kg/m^3)	C Density (Kg/m^3)	O Density (Kg/m^3)
Ammonium nitrate	1,700	595	85	0	1,020
Nitroglycerine	1,600	296	35	254	1,015
PETN	1,800	319	45	342	1,094
TNT	1,700	315	37	629	719
RDX	1,830	693	49	297	791
HMX	1,900	719	51	308	822
Black powder	1,800	190	0	281	610
C4 (RDX-based)	1,640	620	44	266	710
Smokeless powder	1,660	325	39	402	984
Natural rubber	1,300	141	111	726	322
ABS plastics	1,050	0	81	962	0
Silk/Wool fibers	1,440	316	90	271	723
Silk/Wool cloths	200	37	13	97	53
Ground nuts	1,400	252	98	728	315
Nylon 6	1,140	161	111	142	0
Nylon 11	1,140	142	111	726	161
Nitrate rubber	1,000	679	121	57	264
Melamine	1,800	1,200	86	514	0
Orlon	1,180	312	67	801	0

Source: Hussein, 1992.

alarm[1] rates (NRC, 1993). Current trace detection instruments are designed to detect particulate amounts of material, which reduces the potential for nuisance alarms considerably.

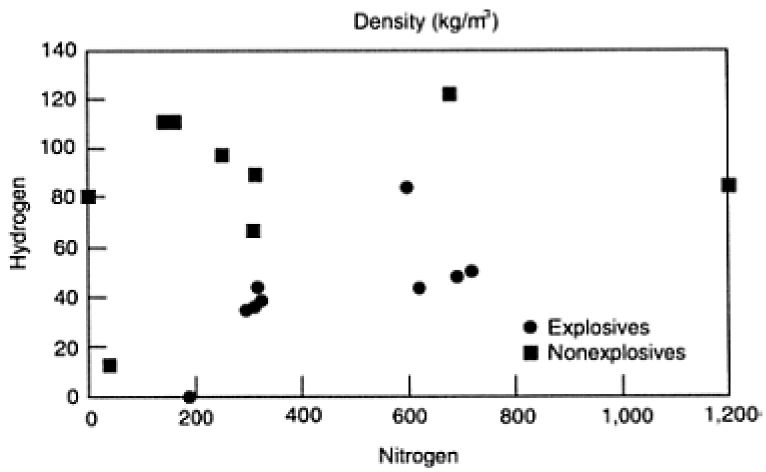


Figure A-1 Hydrogen and nitrogen content of various explosive and nonexplosive materials.
Source: Hussein, 1992.

Mass Density and Composition of Various Explosive and Nonthreat Materials

As discussed in Chapter 3, bulk explosives-detection techniques often exploit the high nitrogen and oxygen densities found in explosives. These elements are also present in nonthreat materials such as plastics, clothing, and narcotics. The relative densities of hydrogen, nitrogen, oxygen, and other elements (e.g., carbon) can be used to discriminate explosive from nonexplosive materials. As can be seen in Table A-1 and Figure A-1, however, each density window in which there is a cluster of explosive materials also includes some nonexplosives.

Conceptual Explosives-Detection System

System Description: An explosives-detection system (EDS) whose principle of operation is predicated on the transmission of light through an object as shown in Figure A-2. The system illuminates one side (input) of the object with visible light. The interaction of light with the object results in a reduced amount of light on the other side of the object (output). The amount of light transmitted through the object is measured with the photodiode, which converts the signal into a physical parameter related to the amount of transmitted light (i.e., electrical current). For this conceptual system, a threat would be represented by an object with very low transmission properties. So detection of a threat relies on a comparison of the value of electrical current observed for the object under illumination with a threshold value of electrical current. The subsystems of this system are presented in Table A-2. The infrastructure for this conceptual explosives-detection system consists of the mechanical stand and electrical interconnections.

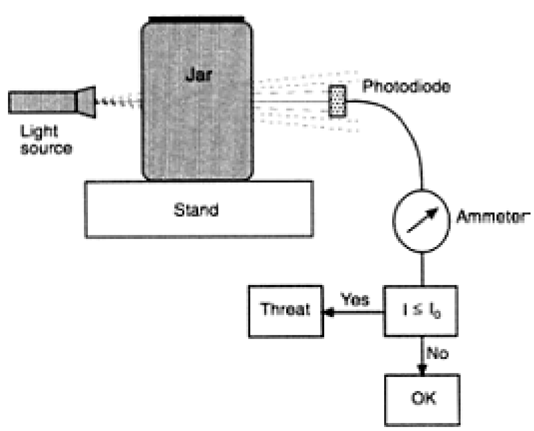


Figure A-2 View of a conceptual EDS based on visible light transmission.

[1] A nuisance alarm is caused when a trace detection instrument correctly identifies the presence of trace amounts of explosive material, but there is not an explosive device present. This may be caused by gun owners having trace amounts of black powder on their hands or miners having trace amounts of dynamite on their hands.

TABLE A-2 Tabular Description of Each Operational Subsystem of a Conceptual EDS Based on Visible Light Transmission

Subsystem	Associated components
Sampling	Flashlight —lightbulb, batteries, lenses, and "on/off" switch Photodiode
Analyzing	Photodiode, ammeter
Classifying	Electrical current comparator —decision based on level of electrical current "Threat" versus "ok" indicators
User Interface	"On/off" light switch "Threat" versus "ok" indicators Ammeter

Note: Individual components may be associated with more than one subsystem.

TABLE A-3 Tabular Description of Each Critical Module of an EDS Based on X-Ray CT

Subsystem	Associated Components
Sampling	X-ray source —x-ray tube, x-ray housing, x-ray collimator, and x-ray filtration X-ray control —x-ray tube current, x-ray tube potential, and exposure time X-ray detector —detector, electronics
Analyzing	Reconstruction algorithms —digital filtration, backpropagation Pattern recognition software
Classifying	Data analysis and manipulation Comparator (human or computer) —decision function and threat notification
User Interface	X-ray status indicators —x-ray "on," thermal heating load, and x-ray tube operating conditions System status indicators —mechanical and electrical Threat notification —audible and visible indicators —retention of image data for operator interpretation

Example of Explosives-Detection System

System Description: An EDS whose principle of operation is x-ray CT, as shown in Figures A-3 and A-4. The subsystems of this system are presented in Table A-3. The system generates an image of the baggage as a map of the x-ray attenuation coefficient in each volume element. The attenuation coefficient depends on the density and the elemental composition of the objects within the baggage. The system then determines the size and shape of any objects whose attenuation coefficient matches that of known explosive materials. Detection of a threat object in the baggage is made when the physical parameters (shape, atomic number, and density) match or exceed predetermined threshold values. The infrastructure of this EDS is the mechanical and electrical framework, including the conveyor system, electrical and mechanical interconnections, and radiation shielding.

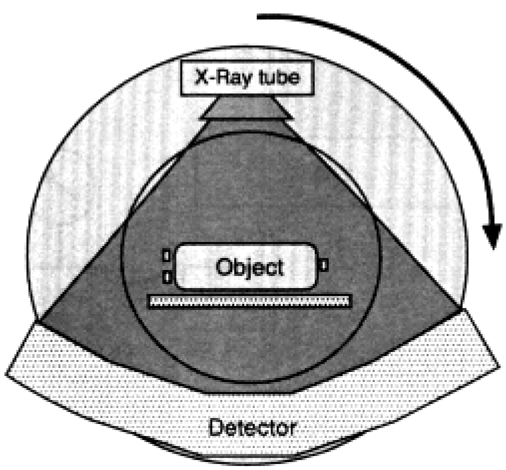


Figure A-3
Front view of an EDS based on x-ray CT.

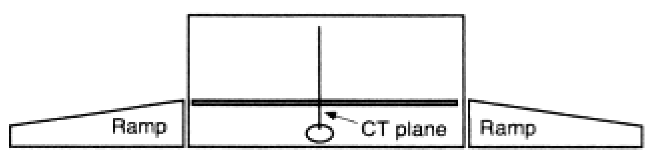


Figure A-4
Side view of an EDS based on x-ray CT.

References

Barfoot, K.M., C.W. Cheng, J.D. MacArthur, B.C. Robertson, S.K. Saha, and K.M. Wilson. 1981. Bulk elemental analysis by the inelastic scattering of neutrons produced with a Van de Graff accelerator. IEEE Transactions on Nuclear Science 28-S(2): 1644-1646.

Gozani, T. 1988. Nuclear detection technology, from plutonium through coal to explosives. American Nuclear Society Transactions 56(3): 38.

Hussein, E.M.A. 1992. Detection of explosive materials using nuclear radiation: a critical review. Pp. 130-137 in X-Ray Detector Physics and Application, R.B. Hoover, ed. Proceedings of The International Society for Optical Engineering, vol. 1736. Bellingham, Wash.: SPIE.

Hussein, E.M.A, P.M. Lord, and D.L. Bot. 1990. An empirical fast-neutron technique for detection of explosive-like materials. Nuclear Instruments and Methods in Physics Research A299(1-3): 453-457.

NRC (National Research Council). 1993. Detection of Explosives for Commercial Aviation Security. National Materials Advisory Board. Washington, D.C.: National Academy Press.

NRC. 1996. Airline Passenger Security Screening: New Technologies and Implementation Issues. National Materials Advisory Board. Washington, D.C.: National Academy Press.

OTA (Office of Technology Assessment, U.S. Congress). 1992. Technology Against Terrorism: Structuring Security. Washington, D.C.: Office of Technology Assessment.

Ovefiey, J.C. 1987. Element-sensitive computed tomography with fast neutrons. Nuclear Instruments and Methods in Physics Research B24/25: 1058-1062.

Appendix B

Configuration Management Tools

The configuration management tool industry is well established in that there are a number of configuration management tools that have gained acceptance in the marketplace (e.g., Pure Atria's ClearCase, Continuus' Continuus, True Software's ADC/Pro, and Intersolv's PVCS, Starbase's StarTeam, MKS's Source Integrity, and Perforce Software's Perforce). Most of these tools are available for Unix and Windows PC platforms. Table B1 shows examples of configuration management tools.

The classification categories for configuration management tools need to match the evolution of a company's development, production, and maintenance needs. For example, a Class 1 tool would typically suit a small company or a research and development group that has a small number of releases and possibly no variant releases. A Class 2 tool would typically suit a medium- or large-sized company that did not have a lot of formal processes defined and was not focused on standards certification. They may have many variant releases and so need strong support for parallel development and build management of products and, therefore, more reliability from the configuration management repository. A Class 3 tool would typically suit a large corporation that had formal processes that need to be automated and that focused on process improvement and had developer and management and change needs similar to companies that use Class 2 tools.

TABLE B1 Examples of Client-Server Configuration Management Tools

Version-Control Tools (Class 1)	Developer-Oriented Tools (Class 2)	Process-Oriented Tools (Class 3)
Intersolv's PVCS	Pure Atria's ClearCase	Continuus' Continuus
MKS's Source Integrity	True Software's ADC/Pro	Platinum's Harvest
Starbase's StarTeam		SQL Software's PCMS (Product Configuration Management Software)
Microsoft's SourceSafe		
Revision Control System (RCS)		
Source Code Control System (SCCS)		
Perforce Software's Perforce		
Tower Concept's Razor		

Appendix C

Threat-Decision Paradigm

A straightforward paradigm from statistical decision-making theory can be used as the framework for a task-based means of evaluating the performance of image-based explosives-detection equipment, such as the InVision CTX-5000. This paradigm can also be used to explain, conceptually, the classification of an explosive threat by other explosives-detection technologies. To assess explosives-detection equipment with this paradigm, a task must be specified (e.g., detection of an explosive threat), and then the ability of the equipment to perform the task must be determined.

Explosives-detection equipment use qualitative and quantitative information extracted from objects within baggage to determine (classify) the presence of an explosive threat. If the information extracted was combined to represent a single physical parameter, the physical parameter can be thought of as a decision variable. The paradigm presupposes a population of explosive threat and normal bags that generates a position and spread (or distribution) of the physical parameter for each population. The overlap of the two populations determines the performance of the equipment. To classify the information obtained from the equipment, a threshold value of the physical parameter is adopted on which to base a decision on the presence of an explosive threat. The threshold value of this physical parameter establishes the detection (true-positive fraction) and false-alarm (false-positive fraction) rates (see Figure C-l). The primary focus of a test and evaluation plan should be those aspects of the explosives-detection equipment that affect the value of the physical parameters that establish the decision threshold.

There are several factors that may contribute to the position and breadth of the distribution of a physical parameter, ultimately determining a detection and false-alarm rate. These contributors include random fluctuations due to statistical processes inherent to data acquisition (e.g., x-ray photon statistics), artificial clutter (noise) resulting from the type and orientation of objects within baggage (e.g., streaks from high atomic number materials in a computed tomography image), mechanical drifts (e.g., bag positioning, resolution degradation), physical and electronics drifts in the x-ray detection and data-acquisition systems, and variation (noise) from different objects within the bag (e.g., clothing, food items, hairdryers) and different types of bags (e.g., nylon, leather, large, small). An estimate of the magnitude of the major contributions to the spread in a physical parameter can be obtained by accessing information at different stages of the explosives-detection process.

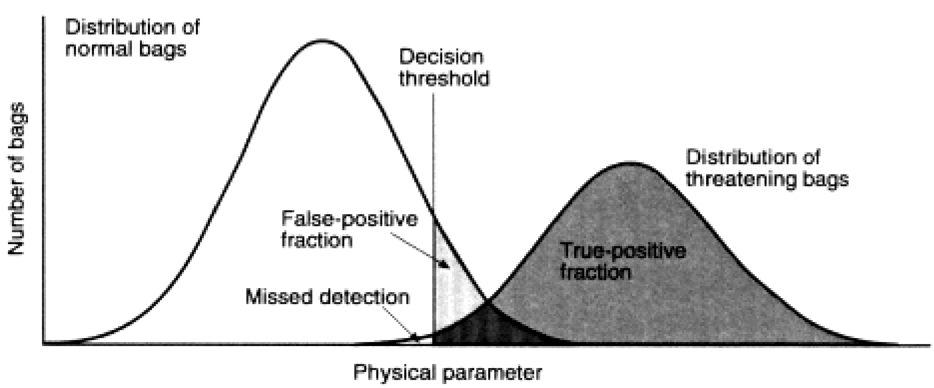


Figure C-1
Schematic drawing of the statistical decision theory paradigm.
Note: This is not representative of the true distribution of threat-containing and nonthreat-containing baggage.

Appendix D

Alternative Quality Standards

FAA Type Certification

FAA Type Certification has primarily been applied to ensure that hardware and software that is manufactured for commercial aircraft is "flightworthy." Throughout the development and manufacturing process, the FAA works with the manufacturer to achieve a product that is acceptable for the intended application.

FAA Type Certification requires that a Certification Program Plan is developed to assist with (1) defining the basis for certification, (2) addressing special conditions, and (3) providing a means to comply with specifications and regulatory requirements. Throughout the certification process, meetings are held between the manufacturer and the FAA to ensure that all FAA requirements are being met. The FAA requires that the manufacturer document and control product development, including design results and reviews, quality-assurance requirements, procurement of materials, and the build of product up to (and including, if necessary) final delivery. Once certified, the manufacturer is granted authority to certify that their product meets FAA standards. Manufacturer compliance is monitored through audits by the FAA or FAA-designated auditors.

The strengths of FAA Type Certification are that it allows the FAA first-hand knowledge of product design, control, and inspection of the product, as well as assurance that the manufacturer's process is under control. FAA Type Certification, however, is labor and resource intensive. Although the manufacturer may benefit from close involvement with the FAA, this arrangement may also constrict development of the product for alternative applications. Furthermore, periodic audits conducted by the FAA (or their designees) involve documentation only, that is, independent performance verification is not required.

Food and Drug Administration's Good Manufacturing Practices

The Food and Drug Administration's (FDA) mandate is to ensure the safety and effectiveness of medical devices through premarket submissions and postmarket regulations. Postmarket regulations employed by the FDA include surveillance reports from manufacturers and device users, as well as requirements regarding manufacturing practices.

The Administration's Good Manufacturing Practices (GMP) regulation requires that all medical device manufacturers prepare and implement a quality management program that is appropriate to the specific device manufactured and meets FDA requirements (21 Code of Federal Regulations, 1995). The regulation is used by the FDA to regulate the manufacture of a wide variety of medical devices, such as pacemakers and x-ray-based computed tomography scanners. GMP covers the methods, facilities, and controls used in preproduction design validation, manufacturing, packaging, storing, and installing medical devices. The FDA has a well-defined regulatory role in monitoring the compliance of manufacturers with the regulation.

The manufacturer has some flexibility, however, with respect to development and maintenance of a quality system. The primary elements of a quality system include (1) meeting the requirements of the GMP regulation, (2) identification of device as well as manufacturing process specifications, (3) validation of device design and manufacturing processes, (4) documented control of device manufacturing processes, and (5) feedback on the quality management program through in-process and final device inspection and testing, device complaints (e.g., internal, customers, regulatory), and audits (e.g., internal, customer, regulatory).

The attractive feature of applying the GMP regulation to the manufacture of explosives-detection equipment is that it would allow the FAA to monitor progress of the design, development, and manufacture processes. Furthermore, use of the GMP regulation would allow for feedback regarding existing and potential problems early in the development and manufacturing cycle. This would enable corrective action, resulting in higher-quality product and more-reliable manufacturing processes.

The major shortcoming of the GMP regulation is that it would be labor intensive on the part of the FAA, especially in the case of new explosives-detection technologies. For example, the regulation would require that all changes to explosives-detection equipment be tracked, tested, and re-tested, with close FAA involvement.

The FDA is in the process of revising the GMP regulation to lessen its prescriptive nature, thus bringing it more in line with ISO 9000 series standards.

The FDA recognizes third-party certification to ISO 9001 or 9002 standards as a viable part of regulation. Third-party auditing, however, should not be accepted in lieu of the regulator. The regulator (e.g., FDA) would likely conduct an overview audit for ensuring regulatory compliance, whereas a third-party auditor would ensure that ISO standards were being maintained. This regulatory scenario may lend itself well to FAA regulation of explosives-detection equipment.

Appendix E

Sample ISO 9000 Effort for a 50-Person Company

1. **Document Review**. This is a review (by an ISO 9000 registrar[1]) of an institution's quality manual that fully describes its entire business system. This document can be an upper-level "policy" document or fully detailed about the system (with the exception of assembly/test instructions).
2. **Pre-ISO Certification Actions**. The client has a choice of either a checklist, an initial visit, or a preassessment audit:

   (2a) Checklist. This document gives the registrar some basic knowledge about the company and the level of system implementation.

   (2b) Initial Visit. This is an on-site visit to discuss document review results, tour the facility, and discuss the upcoming logistics for the initial audit; comments may be made about the system, and a report is generated to summarize the discussions.

   (2c) Preassessment Audit. This is a five-day on-site visit to discuss document review results and audit the quality system. After the audit of the quality system is performed, results are recorded and provided to the company. The company may choose to take action on the issues noted (it is highly recommended that they do so, as some of the issues noted may prevent ISO 9000 certification from occurring as quickly as the company may like), but formal corrective action on the issues identified by the registrar is not required.
3. **Initial (certification) Audit**. This is a formal six-day audit of the quality system, with nonconformances (i.e., items that do not meet the applicable ISO standard or the company's internal procedures) issued and formal corrective action required in response prior to recommending/issuing the certificate. Certification is good for a three-year period, with six-month periodical (surveillance) audits performed in order to monitor compliance activity.
4. **Periodical (surveillance) Audit**. This is a formal audit of the quality system, with nonconformances issued and formal corrective action required. These audits require approximately 1.5 days and are performed every six months during the first three-year cycle of the certificate. Several elements are covered during the audit, with the following elements reviewed at *each* audit: management responsibility, quality system, document and data control, corrective and preventive action, and internal quality audits.
5. **Renewal/Certificate Extension Audit (at the end of the three-year cycle)**. The time required will vary, as some audits are an extended periodical audit, whereas other audits can include a complete audit of *all* applicable elements (similar to an initial audit).

The costs of the above items will vary between registrars. The internal costs at the company (the cost of company personnel, equipment, and other resources) will be significantly greater than the cost of the registrar's audit.

[1] A *registrar* is a company that provides ISO 9000 certification services (e.g., Initial Certification Audits), where an employee of the *registrar* who conducts audits is an *auditor*.

Appendix F

Test Protocol for Bulk Explosives-Detection Equipment

Daily Performance Verification

Equipment of the sophistication of bulk explosives-detection equipment will likely have diagnostic procedures designed by the manufacturer that are resident in the instrument. Typically these diagnostic procedures determine if certain parameters (voltage, signal, frequency, etc.) are within certain boundaries. In conjunction with test articles, these diagnostic procedures can test functional capabilities of the equipment. If the test articles and parameter values are defined and supplied by the vendor and are tested during certification and if performance-verification testing are shown to correlate with performance, they could be used as a daily calibration and check of explosives-detection equipment.

An example test is shown in Figure F-1, which is composed of secondary standard materials embedded in a matrix that simulates clothes, books, plastic, etc. The panel is not proposing that the explosives-detection equipment manufacturers or the FAA fabricate or use the test article exactly as shown in Figure F-1. Rather, the test article shown in Figure F-1 is a conceptual example that more closely represents the threat than does a test article that merely determines certain performance metrics of explosives-detection equipment. The main point of this conceptual example is that the development of a standard test article— one that is independent of the equipment being tested within a specific technology area (e.g., x-ray computed tomography [CT])—representative of the threat to aviation security is of critical importance. A collaborative effort between the FAA and explosives-detection equipment manufacturers is needed to develop a standard test article that includes materials representative of explosives and common nonexplosive materials (i.e., items typically found in passenger baggage). Any test article proposed as a standard (for a particular technology area) for performance verification of explosives-detection systems (EDSs) should be validated against the threat materials it is intended to represent using EDSs based on the same technology (e.g., x-ray CT) produced by at least two different manufacturers.

For the case of equipment based on CT (e.g., CTX-5000-SP) one CT slice would be taken at every level (as shown in the side view in Figure F-1) such that the following system performance parameters could be measured while testing the test article: spatial resolution, contrast sensitivity, noise level, or perhaps the probability of detection and the probability of false alarm. Daily testing of bulk explosives-detection equipment, as recommended by the panel, will involve using a test article similar to that described in Figure F-1 at each personnel shift change. Given the condition that baseline parameter values will be known, subsequent test results can be referenced to these values as a measure of system performance. This daily test could be automated such that the operator could simply put the test article in the machine, push a button, and be presented with a "go" or "no-go" message.

Comprehensive Performance Verification

The process recommended by the panel for comprehensive performance verification in the field requires that the FAA establish a testing approach (a protocol) and baseline performance measures that are used to verify the performance of each device or system at the manufacturing site or at an airport. To date only one manufacturer has produced an FAA-certified EDS (i.e., InVision). The EDS is a bulk explosives-detection system (as opposed to a trace-type system). For this reason, the panel has focused on approaches for performance verification of FAA-certified bulk EDS. Much of what follows, however, could be applied to performance verification of noncertified bulk explosives-detection equipment.

For comprehensive performance verification of deployed bulk equipment the panel recommends using a secondary standard bag set to obtain estimates of the probability of detection

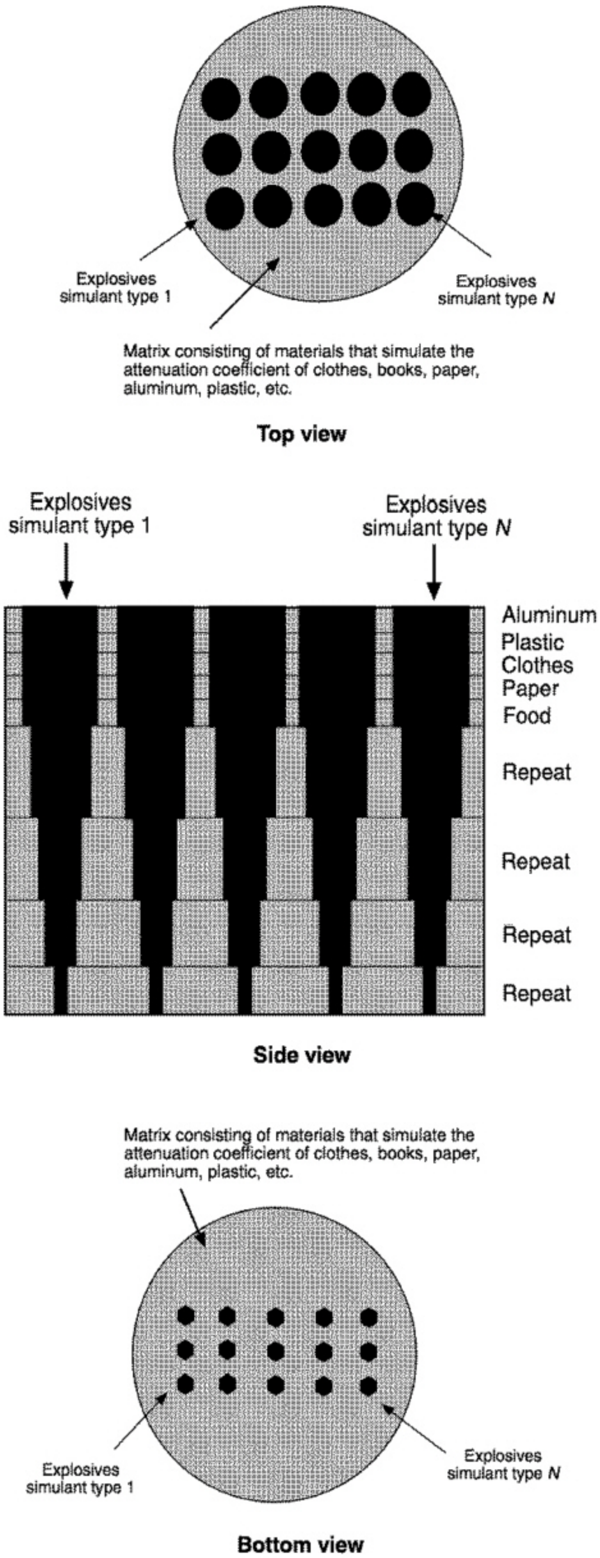


FIGURE F-1 Example standard test article for daily performance verification of bulk explosives-detection equipment. Note: In this test article, *N* different simulated explosives are surrounded by different background materials that simulate common materials found in luggage (e.g., food, clothes, plastic, aluminum, etc.).

(P_D) and the probability of false alarm (P_{FA}) in addition to the P_D and P_{FA} values obtained using the primary standard bag set used in the certification process. This secondary-standard bag set is then used to test and obtain estimates of the probabilities (P_D, P_{FA}) for the deployed explosives-detection equipment. If statistically significant agreement exists between the test with the secondary-standard bag set at the FAA's Technical Center (at the time of certification) and the one at the airport, then the performance of the explosives-detection equipment is said to be verified.

Secondary Standard Bag Set

A secondary standard bag set should be developed by the FAA to consist of a number of representative international passenger bags (that do not contain explosives or simulated explosives) and a number of representative international passenger bags that do contain simulated[1] explosives. These simulated explosives should be validated by the FAA (see Annex II, NRC, 1993) and mimic the real explosives used in the primary standard bag set. This secondary standard bag set should be developed and controlled by the FAA personnel responsible for conducting the certification test and utilized in the conduct of all comprehensive verification testing. All data generated by the use of this bag set should be collected, analyzed, reported, and maintained by the FAA personnel. As the final phase of certification testing, the FAA should test explosives-detection equipment against the secondary standard bag set to obtain estimates of P_D and P_{FA}. The bag set and the data collected would be retained by the FAA as the baseline performance-verification data base. The FAA should make this secondary standard bag set large enough to yield statistically meaningful data, yet small enough to be manageable in terms of transporting the bags from the FAA Technical Center to the various sites. Furthermore, it is desirable to be able to conduct the test in a reasonable amount of time so as not to interfere with routine airport and airline operations. For example, a secondary standard bag set that is 20 percent of the size of the primary standard bag set (which totals some 2,150 bags) would result in a secondary standard bag set consisting of 430 bags. This would yield estimates of P_D and P_{FA} with a standard error $5^{1/2}$ (2.236) times larger than the error in estimated P_D and P_{FA} obtained using the primary standard bag set. In general, if the secondary standard bag set is $1/N$ of the size of the primary standard bag set, the standard error of the estimate will be $N^{1/2}$ times larger.

[1] The panel believes that the FAA, in cooperation with the EDS manufacturers, should develop such simulants for the various technologies being considered or used for bulk EDSs. These simulants should be made available to the developers of the EDS so that they can be used in the process of early determination of the detection capabilities of the technology.

Statistical Analysis

After the physical testing has been completed (i.e., the secondary standard bag set has been tested by the explosives-detection equipment), the following statistical tests should be performed:

- Test that the performance probabilities for the to-be-deployed explosives-detection equipment are statistically equal to or better than the baseline values of the equipment.
- Test that a "significant" number of the bags in the secondary standard bag set are correctly classified by both the explosives-detection equipment that underwent certification testing and the explosives-detection equipment being tested in the field.

The former test will be used in the following example. Testing the hypothesis that the false-alarm rate of the explosives-detection equipment to be deployed is less than or equal to that of the equipment certified by the FAA (with M bags in the secondary standard bag set used for estimating P_{FA}- p_{FA}) with an error of the first kind of 5 percent, the value of the Y statistic is given by the following equation:

$$Y = -1.64^* \{[P_{FA}(1 - P_{FA}) + p_{FA}(1 - p_{FA})]/M\}^{0.5}$$

where P_{FA} is the false-alarm rate observed at certification and p_{FA} is the false-alarm rate observed on the to-be-deployed equipment. If P_{FA}- p_{FA} is greater than or equal to *Y*, then one would have no reason to reject the hypothesis that the "population" value of the false-alarm rate of the to-be-deployed equipment is less than or equal to the "population" value of the false-alarm rate of the equipment at certification. This statement is made at the 95 percent level of confidence. As a guide to determining the size of the secondary standard bag set, *M* must be sufficiently large to allow one to assume normality in the distribution of P_{FA}- p_{FA}.

Conducting a similar test using the simulated explosive threat bags, if it can be determined that there is no reason to reject the hypothesis that the population value of the detection rate of the to-be-deployed EDS is greater than or equal to the population value of the detection rate of the EDS at certification (again at the 95 percent level of confidence), then the performance of the to-be-deployed EDS is verified.

Although the above refers to the to-be-deployed equipment, the same approach can be used to verify that the performance of deployed equipment is still at the level (or better) as when the equipment was certified at the FAA.

Reference

NRC (National Research Council). 1993. Detection of Explosives for Commercial Aviation Security. National Materials Advisory Board. Washington, D.C.: National Academy Press.

Appendix G

Biographical Sketches of Panel Members

Harry Martz (chair) is the leader of the nondestructive evaluation research and development thrust area for Lawrence Livermore National Laboratories (LLNL). He received a B.S. degree in 1979 from Siena College and an M.S. and Ph.D. in 1986 from Florida State University. For six years, he led the computed tomography project at LLNL, applying computed tomography and x-ray and proton radiography to material characterization and gamma-ray gauge techniques to treaty verification activities. His current projects include the use of nonintrusive x-ray and gamma-ray computed tomography techniques as three-dimensional imaging tools to understand material properties and analyze radioactive waste forms. He has applied these techniques to the inspection of automobile and aircraft parts, reactor fuel tubes, high explosives, shape charges, and waste-dram contents. The research and development in his group includes the design and construction of scanners and preprocessing, image reconstruction, and analysis algorithms. Dr. Martz is a member of the National Research Council Committee on Commercial Aviation Security and was a member of the Panel on Airport Passenger Screening.

Kate Alvarado is a Lead Assessor at DNV (Det Norske Veritas) Certification, Inc., performing quality-assurance systems audits based on the requirements of ISO 9001 and ISO 9002. She received a B.S. in management science in 1979 and a B.S. in industrial engineering in 1983, both from the Georgia Institute of Technology. She has extensive experience in surveys and auditing in the aerospace industry, including machine shop parts, electronic assemblies, chemical processes, heat treatments, composites, welds, and brazes. Ms. Alvarado has ten years of experience as a quality engineer for several manufacturing companies. In this capacity, she coordinated statistical process control efforts and trained industrial line supervisors and operators in basic statistical process control techniques. She has an extensive background in supplier systems in several industries, ranging from commercial glass manufacturing to commercial and military aircraft manufacturing.

John Baer is the president of International Management & Engineering Consultants (IMEC). He received a B.S. in chemical engineering from City College of New York, an M.S. in chemical and industrial engineering from Iowa State University, and an M.B.A. from Temple University. He is a practicing and registered professional engineer with an international clientele and consulting experience in the fields of manufacturing technology and engineering management. Mr. Baer is a recognized expert in the functioning of the U.S. defense industrial base and its operations in support of the U.S. Department of Defense. While at the Army Materiel Command headquarters, he supported the development and implementation of computer-aided manufacturing and process planning techniques at Army, Navy, and Air Force arsenals. He has served as a consultant or advisor for incorporating various aspects of MIL-Q-9858A, military standards for configuration management planning, and Just in Time & Total Quality Management into several different industries and institutions. In addition, Mr. Baer has managed programs in manufacturing methods and technology, human factors engineering, and explosives-detection systems.

Susan Dart is president of Dart Technology Strategies, a computer software configuration-management consulting firm in Newport Beach, California. Previously, she was vice president of process technology for Continuous Software Corporation in Irvine, California, where she was responsible for software process improvement and product development and support. Ms. Dart received a B.S. in computer science from the Royal Melbourne Institute of Technology, Melbourne, Australia, and an M.S. in software engineering from Carnegie Mellon University. Ms. Dart has spent 19 years in the computer industry, including seven years at the Software Engineering Institute, conducting research, development, and the implementation of software tools—particularly in the configuration management and software development environments. She also has experience developing telecommunications applications and has participated in international standardization efforts for communications protocols and real-time programming.

Robert Gagne of the Food and Drag Administration (FDA) develops methods to assess the efficiency of radiologic imaging equipment with emphasis on x-ray fluoroscopy, mammography, and computed tomography. Dr. Gagne received a B.S. in physics from the University of New Hampshire and an M.S. and Ph.D. in physics from Georgetown University. He has provided technical support to FDA programs in premarket and postmarket decisions pertaining to medical devices, including the use of various measures of diagnostic efficacy. Dr. Gagne developed a set of protocols currently in use nationwide for the testing of computed tomography equipment by FDA personnel. As an FDA regulatory officer, he developed test methods and calculation techniques for field testing a wide variety of x-ray equipment. In addition, Dr. Gagne has taught undergraduate courses in physics and performed academic research in low-energy nuclear physics.

Donald Lebell is a management and engineering consultant with a broad technical background and extensive experience in industry, academia, and government. Dr. Lebell received a B.S. in engineering from the University of California, Berkeley, and an M.S. and Ph.D. in engineering from the University of California, Los Angeles. He specializes in instrumentation and control-systems design, analysis, and simulation; product-market-technology evaluations; strategy and organizational planning; and environmental trends. Dr. Lebell has been a consultant to more than 400 organizations, private and public, large and small, both domestic and international, in Latin America, Japan, the Middle East, and Europe. His consulting experience includes critiquing the design, proposals, and program plan for promoting a developer's pilotless airborne vehicle system; critiquing a fingerprint-matching product for industrial and commercial security markets; and evaluating the progress, benefits, and pitfalls in implementing a "Total Quality Management" program. Dr. Lebell has also been an expert witness and analyst on litigation involving industrial accidents, patents and trade secrets, products liability, and business interruption losses. In academia, he has served as the university research coordinator and as an adjunct professor of management at the University of Southern California as well as an adjunct professor in the graduate schools of engineering at the University of California, Los Angeles, the University of Southern California, and the University of Maryland.

Attain Pfoh, of General Electric Company, has five years of experience managing research and engineering efforts in support of the manufacture of government-regulated, computed-tomography medical imaging equipment. He received a B.S. in physics and an M.S. in nuclear physics from the University of Heidelberg and a Ph.D. in nuclear physics from the Max Planck Institute. He has experience in research and development and system design of diagnostic medical imaging devices. Dr. Pfoh has been issued five patents and has several others pending approval. He is a member of the Elfun Society and has been an adjunct faculty member of the Medical College of Wisconsin.

Anthony Shumskas, of BDM Engineering Services, has 24 years of experience in systems analysis, configuration management, design, development, integration, project and risk management, test and evaluation, requirements definition, acquisition planning and oversight, and standardization activities for software-intensive systems. Mr. Shumskas received a B.S. in aerospace engineering from the Pennsylvania State University and an M.S. in aerospace engineering from the University of Arizona. He has eight years of experience managing multiple large-scale development programs for the U.S. Department of Defense. Mr. Shumskas is an expert on both product and process quality assessments and metrics. He has authored several management plans for implementing and assessing software product metrics. His expertise in software testing and evaluation supported major decisions on the Department of Defense Software Master Plan and Software Technology Strategy. He also has experience in configuration management. Mr. Shumskas has participated in design and production readiness reviews, taught configuration management, and provided oversight of contractor engineering, manufacturing, and test activities.

Michael Story has conducted research on the design, manufacturing, and operation of commercial mass spectrometers for 30 years at ThermoQuest Corporation (formally Finnigan Instruments). He received a B.S. in chemistry from the University of California, Berkeley. Mr. Story is a member of the current National Research Council Committee on Commercial Aviation Security, was a member of the previous Committee on Commercial Aviation Security (1988-1993), and chaired the Panel on Test Protocol and Performance Criteria.

Glossary

Baseline. The term baseline was originally used in engineering surveying to define an established line with fixed direction and end points such that further extensions into unmapped areas could be made. In configuration management, a baseline is a document, formally designated and fixed at a specific time during a configuration item's life cycle. From this baseline, the development of the system can be extended from specifications into design documentation and ultimately into hardware and software items (Buckley, 1993).

Baseline management. Configuration control of the identified baseline.

Baseline test. A test to determine the baseline performance of noncertified explosives-detection equipment. This test will be conducted at the FAA Technical Center with the primary standard bag set.

Bulk explosives-detection equipment. Any explosives detection device or system that remotely senses some physical or chemical property of an object under investigation to determine if it is an explosive.

Certification baseline. Definition of the configuration baseline of explosives-detection equipment (including individual configuration items) at the time of certification.

Certification test. A test conducted at the FAA Technical Center with the primary standard bag set to evaluate the functional and performance capabilities of an explosives-detection system, under realistic operating conditions, against the FAA's certification criteria. An explosives-detection system that meets the FAA's certification criteria is certified and referred to as a certified explosives-detection system.

Change management. The set of management functions necessary to ensure that compatibility is maintained between all items of a system whenever any single item is changed (Blanchard, 1986). This includes change control of a configuration item (e.g., an x-ray detector) after establishment of the configuration baseline.

Computer software configuration item (CSCI). Configuration items that are specific to system software. Each software module, for example, may constitute a separate CSCI.

Configuration auditing. Checking a configuration item or system for compliance with the identified baseline configuration.

Configuration baseline. A document or a set of documents, formally designated and fixed at a specific time and constituting the approved configuration identification of a configuration item. Documents usually refer to specifications and drawings for hardware, firmware, and software and may include listings, flow charts, decision trees, and so on.

Configuration control (change control). The systematic proposal, justification, evaluation, coordination, approval, or disapproval of proposed changes and the implementation of all approved changes to the baseline configuration of a configuration item and its identification documentation. A major function of this element is the administration of a configuration control board.

Configuration control board. A board composed of technical and administrative representatives who recommended approval or disapproval of proposed engineering changes to a configuration item's current approved configuration (DOD, 1995).

Configuration identification. Selection of configuration items and maintenance of the documents that identify and define the baseline of a configuration item or the overall system (e.g., an explosives-detection system). This includes the determination of the types of configuration documentation for each configuration item, the issuance of unique identifiers (e.g., serial numbers) affixed to each configuration item, and the technical documentation that defines the configuration item's configuration.

Configuration item (CI). A collection of hardware, software, and firmware that is a uniquely identifiable subset of the system configuration that represents the smallest portion of the system to be subject to independent configuration management change control procedures (DOD, 1995; Buckley 1993). The CIs may differ widely in complexity, size, and kind. During development and initial production, CIs are those specification items whose functions and performance parameters must be defined and controlled to achieve the overall end-use function and performance (DOD, 1995).

Configuration management. A process that identifies the functional and physical characteristics of a software, firmware, or hardware item during its life cycle, controls changes to those characteristics, and records and reports change processing and implementation status.

Configuration management plan. A document that defines how configuration management will be implemented for a particular acquisition, program, or system (DOD, 1995).

Configuration status accounting. Recording and reporting the implementation of changes to the baseline configuration of a configuration item and its identification documents.

Criticality (of change). Refers to the "importance" of the item being changed to system performance.

Degree (of change). Refers to the extent of a change (e.g., localized versus all encompassing).

Explosive. A chemical compound that reacts rapidly, generating substantial amounts of heat and pressure.

Explosives-detection device. An instrument that incorporates a single detection method to detect one or more explosive material categories.

Explosives-detection equipment. Any equipment, certified or otherwise, that can be used to detect explosives.

Explosives-detection system (EDS). A self-contained unit composed of one or more devices integrated into a system that has passed the FAA's certification test.

Life cycle. The total phases through which an item passes from the time it is initially developed until the time it is either consumed in use or disposed of as being excess to all known materiel requirements (DOD, 1995).

Life-cycle management plan. As used in this report, the management plan is a plan that will reside with and be maintained by the FAA that defines and documents the FAA's configuration management, performance-verification, and quality-assurance requirements for the FAA during certification and field testing of explosives-detection equipment (this would include control of test articles, procedures (documentation), and test results) explosives-detection equipment manufacturers during the engineering, manufacturing, and operational life cycles the airlines and other end users, with regard to deployed explosives-detection equipment, during the operational life cycle (this would include control of operating and maintenance procedures)

Monitoring. Monitoring of critical system parameters to determine if performance of explosives-detection equipment has changed. Monitoring would normally be done in the airport at specified intervals using test articles to demonstrate to the user and the FAA that equipment performance has not changed.

Performance verification. As used in this report, the process to verify that explosives-detection equipment complies with the requirements allocated to it.

Precertification testing. The precertification test provides quantitative evidence that an explosives-detection system meets (or fails to meet) the FAA's performance requirements prior to certification testing. This test is used to determine if an explosives-detection system is ready for certification testing.

Primary standard. In this report, refers to any explosive material identified by the FAA that must be detected by an explosives-detection system for such a system to be certified.

Primary standard bag set. In this report, refers to the standard bag set that the FAA uses for certification testing of every explosives-detection system submitted. The primary standard bag set consists of representative passenger bags, some of which contain explosives at threat quantity.

Qualification test. The purpose of the qualification test is to verify the performance of an individual explosives-detection system unit to qualify that unit for deployment.

Quality standard. Defines the requirements of a quality system, for example, ISO 9001.

Quality system. The total quality system is the agreed company-wide and plant-wide operations work structure, documented in effective, integrated, technical, and managerial procedures, for guiding the coordinated actions of the work force, the machines, and the information of the company and plant in the best and most practical ways to assure customer quality satisfaction and economical costs of quality (Feigenbaum, 1983).

Regression testing. The process of validating modified parts of a software program and ensuring that no new errors are introduced into a previously tested code. Although software may have been completely tested during its development, program changes during maintenance require that parts of the software be tested by a regression test.

Secondary standard. In this report, a nonexplosive material that simulates the physical characteristics (e.g., average atomic number, density, etc.) of an explosive such that when characterized by a particular explosives-detection technology it appears to be an explosive.

Secondary standard bag set. In this report, a secondary standard bag set consists of a number of representative international passenger bags that do not contain threat objects and a number of bags containing simulated explosives at an amount that represents a threat quantity of explosives.

Self-diagnosis test. A test to determine if components or subsystems of an explosives-detection system are functional. Self-diagnosis includes the continuous measure ment of subsystem parameters (e.g., voltages and currents) during routine operation as well as self-diagnostic routines on machine start-up.

Status accounting. Recording and reporting proposed and approved changes to the baseline configuration of a configuration item and its identification documents. This includes a record of the approved configuration item documentation and identification numbers, the status of proposed changes to configuration item configuration, and the implementation status of approved changes.

Test articles. Individual articles, including items such as simulants, the InVision IQ simulants test bag, and ASTM (1993) standardized step wedges and computed tomography phantoms. The purpose of these articles is too elicit a predetermined response to test critical system parameters.

Test objects. Any object (or objects) that is used to test the performance of an explosives-detection system. For example, the primary standard bag set, the secondary standard bag set, simulated explosives, etc.

Trace explosives-detection device. A device that detects explosives through direct chemical identification of particles or vapors given off by explosive materials.

Validation. Confirmation that the specified requirements (for an explosives-detection system) satisfy stakeholder needs.

Verification. Confirmation that an explosives-detection system fulfills the specified requirements of the stakeholders.

Verification testing. Determines if a deployed explosives-detection system meets its performance requirements. Verification testing would normally be performed in the airport at initial deployment and at specified intervals using a secondary standard bag set to demonstrate to the user and the FAA that the unit is functioning as specified.

Version control. Documentation and control of individual versions of objects, such as software source code, executables, graphics, x-ray sources, detectors, etc.

REFERENCES

ASTM (American Society for Testing and Materials). 1993. Design and Use of Ionizing Radiation Equipment for the Detection of Items Prohibited in Controlled Access Areas. F792-88. West Conshohocken, Pa.: American Society for Testing and Materials.
Blanchard, B.S. 1986. Logistics Engineering and Management, 3rd ed. Englewood Cliffs, N.J.: Prentice-Hall.
Buckley, F.J. 1993. Implementing Configuration Management: Hardware, Software, and Firmware. Piscataway, N.J.: IEEE Press.
DOD. 1995. Configuration Management. MIL-STD-973. Washington, D.C.: U.S. Department of Defense.
Feigenbaum, A.V. 1983. Total Quality Control, 3rd ed. New York: McGraw-Hill.

Technical Report Documentation Page

1. Report No, DOT/FAA/ AR-98/51	2. Government Accession No.	3. Recipient's Catalog No.	
4. Title and Subtitle Configuration Management and Performance Verification of Explosives-Detection Systems		5. Report Date September 1998	
		6. Performing Organization Code National Research Council	
7. Author(s) Committee on Commercial Aviation Security Panel on Technical Regulation of Explosives-Detection Systems		8. Performing Organization Report No. NMAB-482-3	
9. Performing Organization Name and Address National Materials Advisory Board National Research Coucnil 2101 Constitution Avenue, NW Washington, DC 20418		10. Work Unit No. (TRAIS)	
		11. Contract or Grant No. DTFA03-94-C-00068	
12. Sponsoring Agency Name and Address Federal Aviation Administration Technical Center Aviation Security Research and Development Service Atlantic City International Airport, NJ 08405		13. Type of Report and Period Covered Final Report	
		14. Sponsoring Agency Code AAR-500	
15. Supplementary Notes The FAA's Contracting Officer's Technical Representatives (COTR) are Alan Novakoff and Paul Jankowski			
16. Abstract Aviation security is being expanded to include commercial equipment that is capable of detecting the presence of explosives in passenger baggage. The FAA is developing procedures to ensure that explosives-detection equipment is manufactured, maintained and operated in a manner that will perpetuate an acceptable level of performance. This report examines options for verifying the performance of this equipment and ensuring that changes or upgrades to such equipment are properly managed.			
17. Key Words explosives detection systems, aviation security, bulk explosives detection technology, trace explosives detection technology, configuration management, performance verification, quality control	18. Distribution Statement		
19. Security Classif. (of this report) Unclassified	20. Security Classif. (of this page) Unclassified	21. No. of Pages 88	22. Price
Form DOT F1700.7 (8-72)	**Reproduction of completed page authorized**		