Department of Homeland Security Office of Inspector General

Transportation Security Administration's Use of Backscatter Units



February 2012

Office of Inspector General

U.S. Department of Homeland Security Washington, DC 20528



February 14, 2012

Preface

The Department of Homeland Security (DHS) Office of Inspector General (OIG) was established by the *Homeland Security Act of 2002* (Public Law 107-296) by amendment to the *Inspector General Act of 1978*. This is one of a series of audit, inspection, and special reports prepared as part of our oversight responsibilities to promote economy, efficiency, and effectiveness within the Department.

This report addresses the strengths and weaknesses of the Transportation Security Administration's use of backscatter units. It is based on interviews with employees and officials of relevant agencies and institutions, direct observations, and a review of applicable documents.

The recommendations herein have been developed to the best knowledge available to our office, and have been discussed in draft with those responsible for implementation. We trust this report will result in more effective, efficient, and economical operations. We express our appreciation to all of those who contributed to the preparation of this report.

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Abbreviations

AIT ANSI APL CDRH	Advanced Imaging Technology American National Standards Institute Applied Physics Laboratory Center for Devices and Radiological Health
DHS	Department of Homeland Security
FDA	Food and Drug Administration
HPS	Health Physics Society
JHU	Johns Hopkins University
mrem	millirem
NIST	National Institute of Standards and Technology
OIG	Office of Inspector General
OJT	on-the-job training
OLC	Online Learning Center
OSHE	Office of Occupational Safety, Health and Environment
RSO	Radiation Safety Office
S&T	Science and Technology
SAT	Site Acceptance Test
TSA	Transportation Security Administration
TSO	Transportation Security Officer
μrem	microrem
USAPHC	U.S. Army Public Health Command

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Executive Summary

The Transportation Security Administration is responsible for screening passengers at commercial airports. One method of securing the traveling public is through the use of Advanced Imaging Technology to detect a wide range of metallic and nonmetallic threats, including weapons and explosives. The general-use backscatter unit is a type of imaging technology that delivers an extremely low dose of ionizing radiation to the person being screened. These units create an image from very small amounts of x-ray that reflect off the person being screened.

The Transportation Security Administration began deploying general-use backscatter units in March 2010, with 247 units currently operating in 39 commercial airports around the country. Advanced Imaging Technology equipment used by the agency must conform to requirements established by the Health Physics Society and accredited by the American National Standards Institute, an entity responsible for facilitating the development of national radiation safety standards.

Professional organizations conducted independent radiation studies that concluded that radiation levels emitted from backscatter units were below the acceptable limits. Specifically, to reach annual radiation dose limits, a passenger would have to receive more than approximately 17,000 screenings in a 12-month period, which is equivalent to approximately 47 screenings per day, 365 days per year. The Transportation Security Administration entered into interagency agreements for additional radiation safety surveys and dosimetry monitoring studies to document radiation dose to agency personnel and individuals undergoing screening. The results of each study concluded that the level of radiation emitted was below acceptable limits.

We are making recommendations for the Transportation Security Administration to (1) ensure that radiation surveys are conducted on backscatter units for any incidents of unintended radiation emissions, (2) ensure that backscatter calibrations are consistently conducted and documented, (3) ensure that Transportation Security Officers complete annual radiation safety training, (4) verify that training requirements are completed, (5) determine the appropriate amount of on-the-job training for Transportation Security Officers who operate backscatter units, and (6) develop procedures to ensure appropriate notifications of unintended radiation emissions or overdoses.

Background

The Transportation Security Administration (TSA), the primary agency responsible for securing the Nation's civil aviation enterprise, is responsible for screening passengers at commercial airports throughout the United States and its territories. Passenger screening is carried out by Transportation Security Officers (TSOs) trained to perform screening duties. In addition to TSOs at federal airports, nonfederal airports use private contract screeners for passenger screening with TSA oversight. Guidance from TSA's screening policies and training requirements for TSOs also applies to contract screeners at nonfederal airports.

TSA's Passenger Screening Program manages security technology processes for passenger screening at airport security checkpoints to prevent the entry of dangerous and prohibited items on commercial aircraft. Advanced Imaging Technology (AIT) equipment is used to screen passengers for metallic and nonmetallic threats that include weapons, explosives, and other prohibited objects concealed on individuals entering secure areas of the airport. The general-use backscatter unit shown in figure 1 is one type of AIT equipment used for passenger screening.¹

Figure 1. Backscatter Unit



Source: TSA.

Backscatter units are categorized as general-use systems—systems that ensure a high degree of radiation safety based on the emission of negligible doses of radiation and built-in engineering controls.

Unlike a traditional x-ray machine, which relies on the transmission of

¹ Millimeter wave technology is the other AIT used by TSA. It consists of non-ionizing electromagnetic waves that generate images based on energy reflected from the body.

x-rays through the object, general-use backscatter units detect the radiation that reflects off the object and forms an image. The backscatter pattern is dependent on the material property, which makes it suitable for imaging organic material. General-use backscatter units rapidly scan an x-ray beam over an individual's body, electronically creating an image from x-rays that scatter from the skin's surface. The technology displays the front and back images of the scanned individual, which a TSA image operator analyzes to identify potential threats.

General-use backscatter technology using x-ray exposes the person being scanned to negligible doses of ionizing radiation. When a person is exposed to radiation, energy is deposited in the tissues of the body. The amount of energy deposited per unit mass of human tissue is called the absorbed dose. The effective dose of radiation is a measure of the combined effects of radiation on various body tissues and organs.

A person's biological risk—the risk of suffering health effects from exposure to radiation—is measured in rems. A rem is a unit used to describe how much radiation energy an individual receives. When the amount of radiation being measured is less than 1 rem, prefixes are attached to the unit of measure. Smaller radiation doses can be measured in millirems (mrem), which is one thousandth (1/1,000) of a rem, and microrem (µrem), which is one millionth (1/1,000,000) of a rem.

In the United States, an x-ray system is considered compliant with requirements for general-purpose security screening of humans if it complies with standards of the American National Standards Institute (ANSI). ANSI facilitates the development of national standards by accrediting the procedures of organizations that collaborate in developing national consensus standards. ANSI and the Health Physics Society (HPS), a scientific organization specializing in promoting excellence in radiation safety, collaborated on the radiation safety standard ANSI/HPS N43.17-2002, *Radiation Safety for Personnel Security Screening Systems Using X-Rays*. This standard included requirements intended for self-enclosed, full-body x-ray scanners that operated by scanning a person who was standing still.

Several new x-ray scanning system designs and new use requirements were developed after the publication of ANSI/HPS N43.17-2002, such as systems that scan occupied vehicles and those that inspect casts and prosthetic devices. As a result of these new designs, a revised standard was published in November 2009, ANSI/HPS N43.17-2009, *Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation*.

TSA requires that general-use backscatter units approved for deployment conform to ANSI/HPS N43.17-2009, which provides guidelines specific to radiation safety in the design, performance, and operation of these systems, and covers dose to subject, operational procedures, training for operators, and other information. The standard includes requirements for (1) general-use full-body scanning systems, such as backscatter units, that scan individuals standing in a fixed position, and (2) the maximum amount of radiation a passenger receives within a 12-month period.

The ANSI/HPS N43.17-2009 committee changed the way the dose limit is stated from 10 microrem for one front scan to 25 microrem for a full screening. ANSI/HPS N43.17-2009 retained the annual effective dose limit of 25 mrem in a 12-month period for scanned individuals. By comparison, 25 mrem is equal to the amount of background radiation exposure from the air and soil at sea level every 1.5 hours. Table 1 lists examples of radiation exposures and the associated doses:

Source of Exposure	Dose in mrem
Exposure to cosmic rays during a roundtrip airplane flight from New York to Los Angeles	3 mrem
One dental x ray	4–15 mrem
One chest x ray	10 mrem
One mammogram	70 mrem
One year of exposure to natural radiation (from soil, cosmic rays, etc.)	300 mrem

Table 1. Examples of Radiation Exposure

Source: Centers for Disease Control and Prevention

According to Rapiscan, the manufacturer, the effective dose for one screening from a backscatter unit is 5 microrem (0.005 mrem) or less.

Radiation surveys required by ANSI standards are conducted to determine the x-ray emissions from general-use backscatter units. Independent, or third-party, surveys of the general-use backscatter units are also performed to measure these emissions and determine whether they comply with ANSI standards and federal regulations. Third-party surveys are in addition to the annual radiation surveys that maintenance providers perform.

Results of Review

Independent Surveys Conducted Prior to Deployment Conclude That Backscatter Radiation Levels Are Below Established Limits

Prior to the deployment of general-use backscatter units in March 2010, TSA entered into agreements with federal agencies and partnered with accredited organizations to determine whether the level of radiation emitted by backscatter units was within ANSI's acceptable limits. Four radiation safety assessments were performed on backscatter units prior to their deployment and use for passenger scanning. The results of each study concluded that the level of radiation emitted was below ANSI's acceptable limits.²

The following sections provide the results of radiation assessments conducted on the backscatter units.

Food and Drug Administration Radiation Safety Assessments

The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) is responsible for the oversight of radiationproducing equipment. CDRH entered into an interagency agreement with TSA in April 2006 to evaluate x-ray emissions from airport screening equipment and estimate the effective dose of radiation to individuals being scanned, AIT operators, and bystanders.³

In July 2006, CDRH determined the effective dose of radiation for individuals scanned by Rapiscan's Secure 1000 backscatter unit. Based on the results of CDRH's study, an adult would receive an effective dose of about 2.4 microrem per scan, a child would receive an effective dose of about 4 microrem per scan, and an infant would receive an effective dose of about 5 microrem per scan. All test results concluded that the effective dose of radiation for individuals scanned was below the ANSI standard of 10 microrem per scan.⁴

Rapiscan's Third-Party Radiation Testing

TSA developed a Qualification Test and Evaluation of Whole Body Imagers to support its procurement decisions prior to awarding the backscatter contract. As the manufacturer of the backscatter unit, Rapiscan submitted a Qualification Data Package, which included a requirement that certification to the ANSI safety radiation levels be performed by a third party, not the manufacturer.

² ANSI/HPS N43.17, Section 2.0.

³ Task Order 001 of Interagency Agreement HSTS04-06-X-CTO003.

⁴ Radiation Safety for Personnel Security Screening Systems Using X-rays (N43.17-2002), July 2002.

Rapiscan redesigned backscatter units from a dual-pose to a single-pose configuration, allowing an individual's front and back to be scanned in succession. This modification required that the backscatter unit be assessed for compliance with ANSI standards by a third-party tester. Therefore, a radiation safety assessment of its newly configured backscatter unit was included as part of the third-party testing.

In a June 2008 report, the third-party tester assessed radiation levels for scanned individuals and backscatter operators. The report concluded that the redesigned backscatter unit met ANSI standards of less than 10 microrem per scan. For the backscatter unit, the effective dose of radiation for individuals per scan was 1.81 microrem, and the effective dose for operators was approximately 0.68 microrem. Although the units met ANSI safety standards, the third-party tester recommended that wing shields be installed to further reduce radiation exposure levels for backscatter operators.

National Institute of Standards and Technology

The National Institute of Standards and Technology's (NIST) Office of Law Enforcement Standards maintains expertise in developing electronic instruments that detect contraband on an individual's body or under clothing. To support the research efforts of DHS' Science and Technology (S&T) Directorate, DHS has an interagency agreement with NIST to provide reviews, audits, and technical support for TSA and S&T's Transportation Security Laboratory's testing of enhanced metal detectors, which includes backscatter units.

In July 2008, NIST assessed the backscatter unit's radiation safety level and its compliance with ANSI N43.17-2002. Based on a review of Rapiscan's third-party tester's compliance reports, backscatter unit specifications, and results from the FDA CDRH assessment of the original backscatter configuration, NIST concluded that radiation levels for scanned individuals were below ANSI limits. NIST also agreed with Rapiscan's third-party tester's June 2008 recommendation to add wing shields to further reduce backscatter operators' exposure to radiation.

Rapiscan's Third-Party Supplemental Report

Based on recommendations from the third-party tester and NIST, Rapiscan modified the backscatter unit in August 2008 by attaching wing shields on each side to minimize operators' exposure to radiation. Because of the ANSI requirement to test units after any update or modification, Rapiscan's third-party tester retested the modified backscatter unit to determine

whether radiation exposures to operators were in compliance with ANSI dose limitations after the addition of wing shields.

In October 2008, Rapiscan's third-party tester provided a supplement to the June 2008 report, which concluded that the operator dose was approximately 0.02 microrem per scan, which is less than the 10 microrem per scan limit established by ANSI/HPS N43-17-2002.

Johns Hopkins University Independent Assessment

The Johns Hopkins University Applied Physics Laboratory (JHU/APL) provides technical support to TSA by evaluating x-ray systems used for scanning vehicles and personnel. TSA requested that JHU/APL conduct an independent radiation safety engineering assessment of the backscatter unit to determine compliance with ANSI.⁵

JHU/APL conducted its assessment from July 27 through 29, 2009. ANSI/HPS N43.17-2002 was in effect during this period. Under this standard, the limit of the effective dose per scan was 10 microrem. However, a revised standard, ANSI/HPS N43.17-2009, was pending publication during the time of that assessment. This new ANSI/HPS standard changed the effective dose from 10 microrem for one front scan to 25 microrem for a full screening. JHU/APL applied both ANSI standards as part of its assessment methodology.

In October 2009, JHU/APL released the results of both assessments. When applying the requirements of the 2002 ANSI standard, the assessment determined an individual effective dose per scan of 1.58 microrem. Therefore, an individual who receives fewer than 15,822 screenings in a 12-month period, which is equivalent to 43 screenings per day, 365 days per year, will not reach the annual effective dose of 25 mrem. Using the 2009 standard, the assessment determined an individual effective dose of 1.48 microrem per screening. An individual effective dose is below the 25 mrem annual limit for individuals with fewer than 16,891 screenings in a 12-month period, which is equivalent to 46 screenings per day, 365 days per year.

The background exposure reading was revised in an August 2010 JHU/APL report that changed the average effective dose per screening from 1.48 microrem to 1.46 microrem, and the individual effective dose from 16,901 to 17,123 screenings in a 12-month period. The 2009 and 2010 calculations were both below the annual limit.

⁵ ANSI N43.17-2002 and ANSI/HPS N43.17-2009, *Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation*.

TSA Complied With ANSI Radiation Safety Survey Requirements

In addition to establishing radiation levels, the ANSI standard requires that radiation safety surveys be conducted to verify the effective dose, radiation leakage, inspection zone, and any other parameters specified by the manufacturer.⁶ To accomplish these objectives, radiation surveys are required (1) upon installation of backscatter units; (2) every 12 months; (3) after any maintenance that affects the radiation shielding, shutter mechanism, or x-ray production components; and (4) after any incident that may have damaged the unit in such a way that unintended radiation emission occurs. TSA has established procedures to ensure that radiation safety surveys are conducted during specific intervals and when circumstances dictate.

Radiation Safety Surveys at Installation

ANSI N43.17- 2009 requires that radiation safety surveys be performed upon installation of backscatter units. These surveys, referred to as Site Acceptance Tests (SATs), verify that backscatter units are installed and configured properly and that radiation levels are compliant with ANSI standards. The SAT Plans and Procedures lists each specification to be verified and includes the reporting requirements for survey results.

Rapiscan field technicians conducted independent SATs on each backscatter unit deployed to airports. As units were installed, the field technicians recorded SAT results on Form R-0646-1, *Secure 1000 Radiation Emission Measurement Survey*, which was reviewed by Rapiscan's Radiation Safety Office (RSO) and provided to TSA personnel.

In November 2010, TSA received a request from a news organization for the results of radiation safety surveys conducted during the initial installation of backscatter units that began in March 2010. In December 2010, TSA also received a congressional request to release the radiation test results of its backscatter units in response to public concern over possible increases in radiation levels. However, TSA asked Rapiscan to review the survey results prior to any public release.

Rapiscan's RSO reviewed the initial surveys for each backscatter unit and identified miscalculations in determining radiation levels. Although all backscatter units were in compliance with ANSI standards, Rapiscan technicians conducting the initial surveys improperly calculated radiation levels and documented results that exceeded the 25 microrem ANSI limit. Other errors included excluding background radiation levels and using incorrect scan times.

⁶ The inspection zone is the entire area between the backscatter's two scanning units, including the rubber mat.

RSO employees concluded that the survey reporting form needed clarification, and Rapiscan technicians required additional training on how to complete the forms. Therefore, RSO personnel recommended revising the survey form and providing refresher training for service technicians by January 31, 2011.

In January 2011, TSA collaborated with Rapiscan to revise the survey form and automate the mathematical formulas in order to electronically calculate radiation levels. Rapiscan training records indicated that technicians attended refresher training in February and March 2011.

In March 2011, Rapiscan resurveyed all 247 backscatter units deployed at 39 commercial airports to verify that radiation levels were within the ANSI limit of 25 microrem per screening. The resurveys showed that radiation levels for all backscatter units were below ANSI standards. Even though the resurveys provided assurances that the radiation levels of all backscatter units were below ANSI limits, TSA did not have a process in place to consistently review and verify the accuracy of radiation safety results. However, effective August 2011, TSA amended its Rapiscan contract to include a process for reviewing the results of all radiation safety surveys at multiple levels to ensure accuracy, completeness, and compliance with ANSI standards.

The revised contract also requires updates on the status of radiation safety surveys, including (1) radiation surveys performed to date, (2) corrected radiation surveys to date, (3) number of radiation resurveys to date, (4) status of trained and certified technicians for radiation surveys, and (5) upcoming radiation surveys and resurveys.

Radiation Safety Surveys Every 12 Months

ANSI N43.17-2009 requires that radiation safety surveys be conducted at least once every 12 months on x-ray personnel security screening systems. The general-use backscatter units were deployed beginning March 2010, with radiation safety surveys due each year after their respective deployment date. Rapiscan's resurvey of all backscatter units in March 2011 satisfied the ANSI requirement through March 2012.

TSA's August 2011 amended contract with Rapiscan required biannual radiation safety surveys on backscatter units for the first 2 years of warranty coverage. Rapiscan created a database that maintains and tracks its preventive maintenance and survey schedule. The database automatically creates work orders for field technicians assigned to airports to complete required annual and semi-annual surveys. Once a radiation survey is completed, the database automatically generates a new work order, dated 6 months in advance, for the next required survey. The amended contract also requires Rapiscan to conduct a final radiation survey for each backscatter unit a month before the warranty expires.

The biannual radiation safety survey schedule established by TSA and Rapiscan provides a mechanism for deployed backscatter units to be surveyed twice within 12-month intervals. This schedule exceeds the ANSI requirement for performing radiation surveys at least once every 12 months.

Radiation Safety Surveys After Maintenance

ANSI requires that radiation safety surveys be conducted on backscatter units after any maintenance that affects the radiation shielding, shutter mechanism, or x-ray production components. Since all backscatter units are under warranty, Rapiscan, as the manufacturer, is responsible for conducting the surveys.

In collaboration with TSA, Rapiscan developed a *Maintenance Manual* to ensure that backscatter units comply with ANSI standards. The manual contains instructions for performing corrective maintenance, and indicates the type and frequency of preventive maintenance activities. Although the manual is primarily used by Rapiscan's contract technicians, it also directs TSA personnel to periodically perform inspections of the backscatter's exterior to determine whether parts may be damaged, missing, or worn.

The maintenance manual describes the corrective and preventive maintenance to be performed on backscatter units. Corrective maintenance is an unscheduled activity performed to restore backscatter units to an operating condition after a system failure. Preventive maintenance consists of periodic scheduled checks to ensure that backscatter units remain reliable and operate as intended. These maintenance activities are conducted by qualified service providers at predetermined intervals.

A database is used to schedule preventive maintenance on backscatter units every 6 months. After preventive maintenance is completed, the database generates another work order for the next 6-month period.

TSA's backscatter maintenance log showed that, from May 2010 to May 2011, 3,778 service calls were made in response to mechanical problems with backscatter units. Of that number, 84, or 2%, resulted in radiation safety surveys. The three most prevalent corrective actions taken to resolve mechanical problems were replacing parts where no adjustments to the units were required (680), rebooting or resetting the unit (566), and replacing parts where adjustments or calibrations were required (528). We

did not identify any instances where a radiation survey should have been performed but was not.

Radiation Safety Surveys After Unintended Emissions

ANSI standards require that radiation safety surveys be conducted on backscatter units after any incident that may have damaged the system and caused unintended radiation emission. We did not identify any instances of unintended radiation emissions.

According to TSA's *Occupational Safety and Health Manual*, safety measures to ensure that unintended radiation emission does not occur include system controls such as interlocking doors, emergency on/off switches, warning labels, and standard operating procedure for the safe use of radiation screening systems.

TSA's *Maintenance Manual* directs all personnel responsible for maintaining backscatter units to provide TSA with a detailed written report of any actions by backscatter users or operators that could cause a radiation accident or unsafe event as soon as such an action is identified. Maintenance personnel are also required to respond to and investigate all reports of system malfunctions or failures and resolve problems before units are back in service.

Rapiscan personnel stated that no contingency plans existed for unintended radiation emissions because safety features were built into backscatter units. Specifically, the failure of any subsystem results in non-operation of the x-ray generator to prevent accidental exposures. TSA personnel also said that a process to handle unintended radiation emissions has not been established since backscatter units were designed not to exceed the ANSI dose limit.

During our fieldwork, we were not informed of any unintended radiation emissions, and we did not identify any reports or other documents that included information related to unintended radiation emissions. However, even with safety requirements that include fail-safe controls, TSA needs to ensure that radiation surveys are conducted after any incident that may damage the system and cause unintended radiation emissions.

Recommendation

We recommend that the Assistant Administrator for Security and Technology, Transportation Security Administration: **<u>Recommendation #1</u>**: Develop a process to ensure that radiation surveys are conducted on general-use backscatter units after any incident that may have damaged the system and caused unintended radiation emissions.

Management Comments and OIG Analysis

We evaluated TSA's written comments and made changes to the report where we deemed appropriate. A summary of TSA's written responses to our recommendations and our analysis of the responses follow each recommendation. A copy of TSA's response, in its entirety, appears in appendix B.

TSA Response: TSA concurred with Recommendation 1.

TSA's current safety protocols require all equipment manufacturers to comply with nationally recognized safety standards to ensure both passenger and operator safety. Each backscatter unit undergoes a system inspection and radiation survey before leaving the manufacturer and after installation in the airport. Radiation surveys are also performed once every 6 months; whenever a unit is moved; after any maintenance action that affects radiation shielding, shutter mechanism, or x-ray production components; and after any incident that may have damaged the system. TSA partnered with Certified Health Physicists at the U.S. Army Public Health Command (Provisional) to conduct independent radiation surveys and inspections to confirm the regular testing performed by the equipment manufacturer.

<u>OIG Analysis</u>: TSA's response describes Rapiscan's responsibility for compliance with federal safety standards relating to damaged backscatter units that may cause unintended radiation emission, and when radiation safety surveys should be conducted. Although there have been no instances of unintended radiation emissions, TSA's oversight responsibilities should include a process to verify that protocols in place are followed in the event of such occurrences. Therefore, this recommendation is **unresolved and open**, pending our receipt and review of such a process.

Radiation Surveys and Studies Conducted After Deployment Conclude That Levels Are Within Established Limits

In 2010, TSA's Office of Occupational Safety, Health and Environment (OSHE) and U.S. Army Public Health Command (USAPHC) extended an established interagency agreement to include USAPHC conducting radiation safety surveys of deployed backscatter units. The agreement also required USAPHC to provide

radiation dosimetry monitoring studies to document the radiation exposure levels of TSA personnel.⁷

USAPHC's radiation safety surveys of backscatter units are not an ANSI requirement, but supplement surveys conducted before and at the time of installation. As part of OSHE's radiation safety program, the surveys are conducted to ensure that backscatter units are in compliance with the 25 microrem per screening limit required by ANSI/HPS N43.17-2009. Radiation safety surveys and dosimetry studies completed by USAPHC concluded that backscatter units were in compliance with the ANSI limit.

USAPHC Radiation Safety Surveys

In April 2010, USAPHC began conducting radiation safety surveys on backscatter units to determine the radiation dose to individuals being screened, system operators, and bystanders. According to test results, all machines surveyed emitted levels of radiation less than the 25 microrem limit per screening. Specifically, the test results concluded that an individual would have to be screened more than 5,000 times in a year to exceed the annual effective dose limit. For system operators and bystanders, the radiation level at the inspection zone would require an individual to be present during 1,000,000 screenings in a year to reach the annual effective dose limit.

USAPHC Dosimetry Studies

From January to Feburary 2011, USAPHC worked with OSHE to conduct an area dosimetry study at TSA's Transportation Systems Integration Facility. This facility assesses various screening systems before and after deployment at airports.⁸

A TSA official explained that USAPHC includes area dosimetry studies during some of the radiation safety surveys. The official said that area dosimetry studies are currently underway at five airports in which dosimeters are mounted on various backscatter units. Data are analyzed by USAPHC and OSHE and incorporated into a final report to OSHE.

During the study, dosimeters were placed in and around a backscatter unit to determine potential radiation doses to TSOs conducting passenger screenings and individuals in close proximity to backscatter units. Preliminary study results showed that the potential radiation dose to backscatter unit operators and individuals in close proximity to the units

⁷ Dosimetry studies measure the potential radiation dose to individuals operating backscatter units as well as to personnel in the vicinity of the units during screening operations.

⁸ Area dosimetry studies measure radiation levels within the immediate area of backscatter units.

was within the ANSI limit. As of August 2011, USAPHC had not submitted a final report to TSA on the dosimetry study.

From April 2010 to August 2011, 145 of the 247 backscatter units deployed nationwide were surveyed. OSHE established a radiation survey schedule through August 2011 that included dates, locations, and durations of each survey. An OSHE official said that plans were underway to survey the remaining backscatter units during fiscal year 2012; however, no specific timeframe for completion has been set.

ANSI standards include a requirement for performing radiation surveys at least every 12 months. Studies performed by USAPHC could provide increased assurance that backscatter units are in compliance with ANSI limits if the interagency agreement included timeframes to survey all backscatter units within a 12-month period.

Backscatter Calibrations Have Not Been Performed Consistently

Backscatter units must be calibrated to ensure appropriate image quality and operational safety. According to TSA's March 2011 *Screening Management Standard Operating Procedures*, calibrations of backscatter units should be performed at defined intervals and under specified circumstances. The procedures provide detailed instructions for recording and maintaining the results of each calibration. However, there were inconsistencies in how TSA personnel adhered to policy requirements.

During our fieldwork, TSA personnel at different airport locations described (1) various frequencies for conducting calibrations at their assigned checkpoint, (2) different scenarios that would require the results to be recorded, and (3) a range of methods for recording calibration results. We did not identify any improperly calibrated backscatter units that compromised operational safety. However, consistency in conducting calibrations and recording the results would provide additional assurance that appropriate safety measures are being enforced.

Recommendation

We recommend that the Assistant Administrator for Security and Technology, Transportation Security Administration:

<u>Recommendation #2</u>: Develop controls to ensure that backscatter unit calibrations are conducted consistently and documented as required by established standard operating procedures.

Management Comments and OIG Analysis

TSA Response: TSA concurred with Recommendation 2.

The Screening Management Standard Operating Procedure, Section 3.2., contains the requirements for the operation, testing, and maintenance of all backscatter and millimeter wave AIT screening equipment. This section also requires that a Supervisory Transportation Security Officer record the results of the daily calibration and image quality verification and that the test records must be maintained for at least 30 days at the checkpoint. After the 30 days, the records must be labeled and maintained for 1 year under the control of the Federal Security Director.

<u>OIG Analysis</u>: TSA's Screening Management Standard Operating Procedures describe how backscatter units should be calibrated and the results recorded. However, we found inconsistencies in the enforcement of these procedures. This recommendation is **unresolved and open**, pending our receipt and review of TSA's measures to ensure uniform compliance with established procedures.

Not All Transportation Security Officers Have Completed Required Radiation Safety Training

ANSI standards require that personnel operating backscatter units receive adequate radiation safety training, followed by refresher training at least once every 12 months. To facilitate completion of this training, TSA has established a centralized online training system for use by TSOs. However, the online system has not been an efficient or effective means of providing radiation safety training or refresher training. As a result, not all TSOs have satisfied the online training requirement for radiation safety.

ANSI standards require that personnel be trained in specific areas that include (1) defining radiation, (2) identifying exposure limits, radiation safety measures, and other safety hazards, (3) procedures to prevent unauthorized use or access to the system, and (4) emergency procedures.

To satisfy ANSI standards, OSHE developed a radiation safety course as part of its Radiation Safety Program. All employees who could be exposed to radiation must complete the most current version of the radiation safety course within 6 months of their initial employment date. In addition, TSOs must retake the most recent version of the radiation safety course every year to satisfy the annual refresher training requirement.

TSA's Online Learning Center (OLC) is a centralized system to support the delivery and management of all TSA learning and development programs. TSA

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policy requires TSOs to complete 2 hours of OLC training each week, including the radiation safety course, to satisfy training requirements. In addition to the online radiation safety training, OSHE officials said TSA promotes radiation safety awareness through bulletins posted on its Intranet site and through the OLC. TSA officials also described other activities, such as Safety Week, in which radiation safety has been a topic of interest during training workshops.

During our fieldwork, several TSOs told us that they were unable to access and complete OLC training because of time constraints associated with performing their duties, or computer delays. They also said that this is why other information concerning radiation safety is not read.

Providing TSOs with an appropriate level of training regarding radiation exposure limits, hazards, and emergency procedures is essential to promote safety. Although TSA provides various resources to inform its employees, it needs to ensure that training resources are effective in satisfying TSO training requirements.

Recommendations

We recommend that the Assistant Administrator for Security and Technology, Transportation Security Administration:

<u>Recommendation #3</u>: Develop a process to ensure that TSOs satisfy ANSI requirements for radiation safety training.

<u>Recommendation #4</u>: Develop a process to verify the completion of annual refresher training by TSOs operating backscatter units.

Management Comments and OIG Analysis

TSA Response: TSA concurred with Recommendation 3.

TSA has developed its training to meet ANSI safety requirements for radiation. All security officers are required to complete radiation safety awareness training on an annual basis. TSA records show that 98% of the security officers at airports with backscatter technology completed the training in fiscal year 2011; the other 2% are not actively screening. Employees' training records are tracked through the TSA OLC.

<u>OIG Analysis</u>: ANSI standards require that operators of backscatter units receive radiation safety training, followed by refresher training at least once every 12 months. TSA established its OLC to manage all TSA learning and development programs. TSA's internal policy requires TSOs to complete 2 hours of OLC training weekly, including the radiation safety course, to satisfy training requirements. However, several actively

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screening TSOs informed us that they were unable to access and complete OLC training due to time constraints associated with performing their duties or computer delays. The TSOs' statements were supported by reconciling their names to a list of radiation-safety trained TSOs. This recommendation is **unresolved and open**, pending our receipt and review of TSA records showing completion of fiscal year 2011 radiation safety training by employees operating backscatter units.

TSA Response: TSA concurred with Recommendation 4.

At the local level, each individual's learning plan contains the required trainings he or she must complete to remain a certified officer. Airport management routinely monitors the training plans of officers to ensure that training is completed by the required completion date. At the headquarters level, training requirements are incorporated into TSA's Management Control Objective Plan. Although this reporting process does not break down completion compliance by individual courses, it alerts executive leadership when an airport's staff is not completing required training. This can prompt leadership to generate reports showing which officers are delinquent and ensure that training is completed. Using both systems to validate completion of training for officers operating all equipment, including backscatter units.

<u>OIG Analysis</u>: TSOs operating AIT equipment must take the most recent version of the radiation safety course each year to satisfy ANSI's annual refresher training requirement. TSA's response addresses all training requirements for TSOs; however, a process to verify whether TSOs operating backscatter units complete the annual radiation safety refresher training is not included. Without such a mechanism in place, TSA has no assurance that radiation safety training will be completed in a timely manner. Therefore, this recommendation is **unresolved and open**.

Additional On-the-Job Training for Transportation Security Officers Should Be Considered

To provide TSOs with the skills necessary to operate backscatter units, TSA developed an AIT training curriculum that includes classroom training and 8 hours of on-the-job training (OJT). Based on information obtained during our field visits, the classroom portion of the AIT training is presented as outlined in the curriculum at all locations. However, there were variances among airports in the OJT provided to prepare TSOs to operate backscatter units without supervisory assistance.

Four of the six airports we visited developed an OJT curriculum that included more than the 8 hours of OJT required in the AIT curriculum. OJT at these airports ranged from 20 to 38 hours. TSOs explained that the AIT classroom curriculum requires understanding a vast amount of knowledge before operating backscatter units, and additional OJT can improve TSOs' competency.

Several TSOs working in airports that required additional OJT hours informed us that they were more comfortable operating backscatter units without supervision as a result of the extra training. Some TSOs who worked in airports that required only the standard 8 hours of OJT said that additional hours would be beneficial before they independently operated backscatter units. A number of TSOs who worked in airports said that the 8 hours of required OJT were sufficient for them to perform their duties effectively.

During our fieldwork, we did not identify TSOs who were not competent to operate backscatter units. However, additional OJT requirements could provide better assurance that TSOs receive training that fully prepares them to operate backscatter units independently.

Recommendation

We recommend that the Assistant Administrator for Security and Technology, Transportation Security Administration:

<u>Recommendation #5</u>: Conduct an assessment to determine the appropriate amount of OJT training for TSOs operating general-use backscatter units.

Management Comments and OIG Analysis

TSA Response: TSA concurred with Recommendation 5.

TSA determined the minimum number of OJT hours required for backscatter units by considering input from subject matter experts, feedback from operational tests and evaluation, and the backscatter course content. This process is used to establish the minimum number of hours to become proficient. The OJT Monitor assesses each officer throughout the OJT process to ensure proficiency in operating the equipment prior to certifying the officer and releasing him or her from OJT. Officers who are not proficient after 8 hours continue with additional OJT until they achieve proficiency.

<u>OIG Analysis</u>: TSA describes the initial process used to establish the minimum number of OJT hours TSOs require to become proficient in the operation of backscatter units. During our fieldwork, some TSOs explained that the 8 hours of OJT was adequate to become proficient in

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operating backscatter units, while other TSOs said they would have been more comfortable if additional OJT hours were available. Most TSOs said the AIT classroom instructions covered an enormous amount of information and additional OJT could be beneficial.

Although we did not find any TSOs who were not competent in the operation of backscatter units, the intent of this recommendation is for TSA to reassess the 8-hour minimum OJT to determine whether additional training should be required. This recommendation will remain **unresolved and open**, pending our receipt of the results of TSA's updated assessment.

Accidental Radiation Overdoses Have Not Occurred

FDA requires immediate notification from manufacturers upon discovery of any accidental radiation occurrence or an equipment safety defect. TSA's amended contract with Rapiscan, dated August 2011, requires immediate notification to TSA and FDA of any accidental radiation emission. Specifically, the amended contract states that radiation safety surveys will be conducted according to the *Federal Food, Drug and Cosmetic Act* and related regulations requiring manufacturers to investigate and report any accidental radiation occurrence to TSA and FDA. However, TSA does not have procedures in place to verify such notifications from Rapiscan to FDA in the event of these occurrences.

According to TSA and Rapiscan personnel, no accidental radiation overdoses of backscatter units have ever occurred. They explained that safety features in backscatter units make it impossible for scanned passengers or TSA employees to receive radiation doses that exceed ANSI standards, because the units immediately default to a shutdown mode when not operating properly.

Our fieldwork did not identify any incidents or reports of accidental radiation emissions or overdoses. However, Rapiscan is required to notify FDA and TSA of any accidental radiation emissions. Therefore, a process to provide such notifications needs to be in place.

Recommendation

We recommend that the Assistant Administrator for Security and Technology, Transportation Security Administration:

<u>Recommendation #6</u>: Develop procedures to ensure FDA is notified of any instances of accidental radiation emissions or overdoses.

Management Comments and OIG Analysis

TSA Response: TSA concurred with Recommendation 6.

Under the provisions of the *Federal Food*, *Drug*, *and Cosmetic Act*, the manufacturer is required to investigate and report any accidental radiation occurrence to the FDA and immediately notify the FDA in the event that the manufacturer becomes aware of a defect. In addition, ANSI/HPS N43.17-2009 requires the manufacturer to establish and maintain records of any incidents involving unplanned exposures as reported by the user, and provide the information to the FDA.

Once backscatter units are out of warranty and TSA becomes responsible for maintenance, the maintenance contractor is required to notify the contracting officer's technical representative and local TSA if a system defect or accidental radiation occurrence is discovered. The maintenance contractor will also notify the manufacturer, who in turn will notify the FDA. Currently, TSA's Director, Occupational Safety, Health, and Environment, "is responsible for coordinating investigations of radiation safety related system defects, damage, malfunctions, and violations of radiation safety procedures." To help ensure that the FDA is notified, TSA will revise the statement to include additional language for notifying the product manufacturer and the FDA whenever any electronic product radiation safety issues meet the criteria of an accidental radiation occurrence or defect.

<u>OIG Analysis</u>: TSA cites the authorities governing notification to FDA in the event of accidental radiation occurrences and describes the actions it will take for these type occurrences when backscatter units are no longer under warranty. However, TSA's oversight responsibilities should include a process to verify that FDA has been properly notified in the event of accidental radiation occurrences, whether or not backscatter units are under warranty. This recommendation is **unresolved and open**, pending our receipt and review of procedures to confirm that FDA is notified of all instances of accidental radiation emissions or overdoses. We conducted this review in response to a request from Congressman Edward J. Markey, U.S. House of Representatives. Our objective was to assess the manner in which TSA inspects, maintains, and operates backscatter units used in passenger scanning. Specifically, we were asked to address (1) the effectiveness and reliability of inspection plans to resolve issues concerning the operation of backscatter units, (2) the efficiency of quality control plans to ensure compliance with the dose-perscreening limit of 25 microrem, (3) how employees are trained to operate backscatter units, (4) how accidental overdose information is shared with federal agencies, passengers, or employees, and (5) TSA's coordination with other federal agencies with more subject matter expertise.

We conducted our fieldwork from February to June 2011 at six airports that used backscatter units as the primary passenger scanning system. These locations were Charlotte, North Carolina; Fort Lauderdale, Florida; Seattle, Washington; San Diego, California; Los Angeles, California; and Boston, Massachusetts.

We interviewed personnel from TSA, S&T, Rapiscan, and USAPHC. We analyzed relevant documents and statistical data relating to backscatter unit radiation safety surveys, quality control measures, TSA training criteria, and coordination and information sharing between TSA and other federal agencies concerning the safety of backscatter units. As part of our analysis, we relied on radiation assessments previously conducted by FDA, Rapiscan, NIST, JHU/APL, and a third-party tester.

To assess the effectiveness of TSA's radiation safety programs, we observed USACPH radiation safety surveys and occupational safety and health inspections at Washington Dulles International Airport. We also visited the TSA Transportation Security Integration Facility at Ronald Reagan Washington National Airport, and the S&T Transportation Security Laboratory, Atlantic City, New Jersey, to determine their role in TSA's radiation safety testing.

This review was conducted under the authority of the *Inspector General Act of 1978*, as amended, and according to the *Quality Standards for Inspections and Evaluations* issued by the Council of the Inspectors General on Integrity and Efficiency.

U.S. Department of Homeland Security 601 South 12th Street Arlington, VA 20598



Transportation Security Administration

INFORMATION

Carlton I. Mann

Assistant Inspector General

MEMORANDUM FOR:

DEC 1 9 2011

FROM:

John S. Pistole Administrator John S. Cisfile Transportation Security Administration

U.S. Department of Homeland Security (DHS)

SUBJECT:

Response to Draft Report, Transportation Security Administration's Use of Backscatter Units, October 2011

Purpose:

This memorandum constitutes the Transportation Security Administration's (TSA's) response to the DHS Office of the Inspector General (OIG) draft report, *Transportation Security Administration's Use of Backscatter Units*, dated October 2011.

Background:

In February 2011, OIG initiated a review of TSA's use of backscatter units in response to a request from Congressman Edward J. Markey, U.S. House of Representatives.

During this review, OIG visited six airports that used backscatter units as the primary passenger scanning system, and interviewed personnel from TSA, DHS Science and Technology (S&T), Rapiscan, and U.S. Army Public Health Command (USAPHC). OIG also analyzed relevant documents and statistical data relating to backscatter unit radiation safety surveys, quality control measures, TSA training criteria, and coordination and information sharing between TSA and other federal agencies concerning the safety of backscatter units.

OIG's report concludes that TSA was in compliance with the standard regarding radiation exposure limits and radiation safety requirements, and identified six recommendations for TSA.

Discussion:

TSA appreciates OIG's work in planning and conducting its review and issuing this report. We believe the report fully endorses TSA's extensive efforts to keep the traveling public safe, which is our agency's ultimate priority.

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As a result of intense research, analysis, and testing, TSA concludes that potential health risks from a full-body screening with a general-use x-ray security system are miniscule. Several groups of recognized experts have analyzed the radiation safety issues associated with this technology and have found the systems to be well below the radiation dose limits. These experts have published recommendations, commentaries, technical reports, and an American national radiation safety standard as a result of their analyses.

TSA has utilized Inter-Agency Agreements with the National Institute of Standard and Technology (NIST) and the U.S. Food and Drug Administration (FDA) to further validate third party radiation studies that all vendors must submit prior to testing. Additionally, the TSA Office of Occupational Safety, Health, and Environment is working with Certified Health Physicists from the U.S. Army Public Health Command to perform radiation safety surveys of the deployed general-use backscatter x-ray advance imaging technologies.

We have based our evaluation on scientific evidence and on the recommendations of recognized experts. As a result of these evidence-based, responsible actions, we are confident that full-body x-ray security products and practices do not pose a significant risk to the public health.

Conclusion:

TSA has already implemented most of the recommendations contained in the report. Our specific response to each recommendation follows.

Transportation Security Administration (TSA) Update to Office of Inspector General (OIG) 11-101, Transportation Security Administration's Use of Backscatter Units December 2011, Update

Recommendation #1: Develop a process to ensure that radiation surveys are conducted on backscatter units after any incident that may have damaged the system and caused unintended radiation emissions.

TSA Concurs: TSA agrees and has already implemented this recommendation. TSA's current safety protocols require all equipment manufacturers comply with nationally-recognized safety standards to ensure the safety of both passengers and operators. Each general-use backscatter x-ray Advance Imaging Technology (AIT) unit undergoes a system inspection and radiation survey before it leaves the manufacturing facility. The manufacturer must perform a radiation survey on each unit once it is installed in the airport. Radiation surveys are also performed once every 6 months; whenever a unit is moved; after any maintenance action that affects radiation shielding, shutter mechanism, or x-ray production components; and after any incident that may have damaged the system. TSA partnered with Certified Health Physicists at the U.S. Army Public Health Command (Provisional) to conduct independent radiation surveys and inspections to confirm the regular testing performed by the equipment manufacturer.

Recommendation #2: Develop controls to ensure that backscatter unit calibrations are conducted and documented as required by established standard operating procedures.

TSA Concurs: TSA agrees and has already implemented the recommendation. The Screening Management Standard Operating Procedure, Section 3.2., contains the requirements for the operation, testing, and maintenance of all backscatter and millimeter wave AIT screening equipment. This section also requires that a Supervisory Transportation Security Officer record the results of the daily calibration and image quality verification and the test records must be maintained for at least 30 days at the checkpoint. After the 30 days, the records must be labeled and maintained for 1 year under the control of the Federal Security Director.

Recommendation #3: Develop a process to ensure that Transportation Security Officers (TSO) satisfy ANSI requirements for radiation safety training.

TSA Concurs: TSA agrees and has already implemented the recommendation. TSA has developed its training to meet American National Standards Institute (ANSI) safety requirements for radiation. All security officers are required to complete Radiation Safety Awareness training on an annual basis. Our records show that 98 percent of the security officers at airports with backscatter technology completed the training in fiscal year 2011. Employees' training records are tracked through the TSA Online Learning Center; the other 2 percent are not actively screening.

Recommendation #4: Develop a process to verify the completion of annual and refresher training by TSOs operating backscatter units.

TSA Concurs: TSA agrees and has already implemented the recommendation. At the local level, each individual's learning plan contains the required trainings he or she must complete to remain a certified officer. Airport management, to include supervisors and training managers, routinely monitor the training plans of officers to ensure training is completed by the required

completion date. At the Headquarters (HQ) level, training requirements are incorporated into TSA's Management Control Objective Plan, which is a summary report rolling up performance data from each airport. Included in that plan is the compliance rate of the officers at each airport to complete required training by the mandated completion date. While this reporting process does not break down completion compliance by individual courses, it does alert executive leadership, both in the field and at HQ, when an airport's staff is not completing required training, which can then prompt leadership to generate reports showing which officers are delinquent and ensure training is completed. Using both systems to validate completion of training is the process developed to verify completion of training for officer's operating all equipment to include backscatter units.

Recommendation #5: Conduct an assessment to determine the appropriate amount of on-thejob-training (OJT) training for TSOs operating backscatter units.

TSA Concurs: TSA agrees and has already implemented the recommendation. TSA determined the minimum number of OJT hours required for backscatter units by considering input from subject-matter experts, feedback from Operational Test and Evaluation, and the backscatter course content. This process is used to establish the minimum number of hours to become proficient. The OJT Monitor assesses each Officer throughout the OJT process to ensure proficiency in operating the equipment prior to certifying the Officer and releasing from OJT. If the Officer is not proficient after 8 hours, the officer continues with additional OJT until proficiency is achieved.

Recommendation #6: Ensure that procedures are established to notify FDA of any instances of accidental radiation emissions or overdoses.

TSA Concurs: The general-use backscatter x-ray system is classified as an electronic product and therefore, the FDA has regulatory authority over the manufacturer under the Electronic Product Radiation Control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). Under this Act, the original equipment manufacturer (OEM) is required to investigate and report any Accidental Radiation Occurrence (21 CFR 1002.20) to the FDA and immediately notify the FDA in the event they become aware of a defect (21 CFR 1003.10). In addition, ANSI/HPS N43.17-2009, paragraph 7.6, *Records To Be Maintained by Manufacturers*, subparagraph (h), requires the OEM to establish and maintain records of any incidents involving unplanned exposures as reported by the user, and provide the information to the FDA.

Once the system is out of warranty and TSA becomes responsible for maintenance, the maintenance contractor is required to notify the Contracting Officer Technical Representative and local TSA if a system defect or accidental radiation occurrence is discovered. The maintenance contractor will also notify the manufacturer, who in turn will notify the FDA. Currently, Section 27.5(a)(11) of the TSA Occupational Safety and Health Manual provides that the Director, OSHE, is responsible for "Coordinating investigations of radiation safety-related system defects, damage, malfunctions, and violations of radiation safety procedures." To help ensure the FDA is notified, we will revise the statement to state: "Coordinating investigations of radiation safety procedures. In addition, notifying the product manufacturer and the FDA whenever he/she becomes aware of any electronic product radiation safety issues that meet the criteria of an accidental radiation occurrence per 21 CFR 1002.20 and/or a defect in an electronic product per 21 CFR 1003.10."

Deborah Outten-Mills, Chief Inspector Jacqueline Simms, Senior Inspector Shawntae Hampton, Inspector Megan Thompson, Inspector Rahne Jones, Inspector

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