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Transportation Security Administration

INFORMATION

MEMORANDUM FOR: Robin Kane
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10/7/10

FROM: Domenic Bianchini
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SUBJECT: Implementation of Johns Hopkins University Applied Physics Laboratory Recommendations for Rapiscan Secure 1000 Single Pose Advanced Imaging Technology

Purpose

This memorandum provides an update on the recommendations from the Johns Hopkins University Applied Physics Laboratory (APL) third party radiation safety assessment of the Rapiscan Secure 1000 Single Pose Advanced Imaging Technology (AIT) system.

Background

The Transportation Security Administration (TSA) takes all measures to ensure the safety and health of the traveling public and TSA employees when purchasing and deploying new technology. Before TSA purchases technology, the technology is validated by manufacturers to ensure it meets national safety standards. TSA communicates those requirements to manufacturers through procurement specifications and engineering reviews. The advanced imaging technology (AIT) equipment TSA purchased and deployed meets the national radiation safety standard and has been validated by third parties to be safe. TSA also conducts site acceptance testing of AIT to ensure individual AIT units meet safety standards. Once installed, TSA ensures the required manufacturer's preventive maintenance is performed by qualified personnel. Certified Health Physicists with the U.S. Army Public Health Command (Provisional) are performing additional radiation safety surveys and area dosimetry studies to ensure continued compliance with radiation safety standards.

In July 2009, at the request of TSA, APL conducted a third party radiation safety assessment of the Rapiscan Secure 1000 Single Pose AIT system. The purpose of the independent assessment was to measure, verify, and report the parameters of system performance against TSA requirements, the American National Standards Institute/Health Physics Society (ANSI/HPS) N43.17-2002, Radiation Safety for Personnel Security Screening Systems Using X-ray, ANSI/HPS N43.17-2009, Radiation

Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation, and CFR Title 21 Chapter I Subchapter J Part 1002, Records and Reports.

The resulting report, titled "Radiation Safety Engineering Assessment Report for the Rapiscan Secure 1000 in Single Pose Configuration" Version 1.0 dated October 2009, is attached. The technology complies with the original and current American national radiation safety standards. The dose per screening to scanned individuals is far below the limit for a general-use system established in ANSI/HPS N43.17-2009. The assessment results reveal that if an individual receives less than 16,129 screenings in a twelve-month period, equivalent to 44 screenings per day (365 days per year), that individual will not reach the annual effective dose limit of 25 mrem (0.25 mSv) per year as established in the national radiation safety standard. In this report, APL also provides TSA with recommendations to ensure that the recommended dose limit for bystanders, operators, and other employees is always met. (ANSI/HPS N43.17-2002, 5.3 and ANSI/HPS N43.17-2009, B.4) That limit of 100 mrem (1.0 mSv) per year is the same as the National Council on Radiation Protection and Measurements (NCRP 1993) recommended dose limit for the general public. As discussed below, this limit could potentially be exceeded only if an individual were to be present in the area 100% of the time for 2,000 hours (a typical work year) and 180 screenings per hour were performed.

During the process of reviewing this report for Sensitive Security Information (SSI) and vendor proprietary information prior to public release, several minor technical corrections were made. These corrections are identified in the errata sheet in the attached updated report Version 2.0 dated August 2010. Furthermore, during review of this document for public release, TSA identified and redacted certain portions as SSI because the disclosure of this information would be detrimental to transportation security in accordance with 49 CFR part 1520. Likewise, limited information contained in the report that would reveal Rapiscan proprietary commercial information was also redacted pursuant to Freedom of Information Act (FOIA) exemption (b)(4), 5 U.S.C. § 552(b)(4). Annotated next to each redaction is the applicable SSI regulatory provision or FOIA exemption (b)(4). The TSA SSI Program Office, Office of Security Operations, Office of Chief Counsel, Office of Occupational Safety, Health, and Environment all reviewed and concur with these redactions. Further, the proprietary redactions in the report were coordinated with Rapiscan.

Discussion

The APL recommendations from the third party radiation safety assessment, along with TSA actions to implement the recommendations are below.

- Recommendation: Measures to Protect Against Exposure Above AIT Units
  Status: Complete

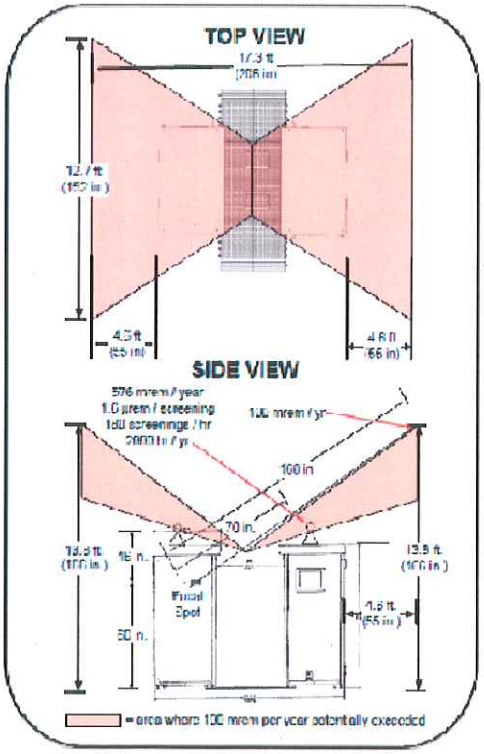
  Issue: APL identified an area above the units where the 100 mrem (1 mSv) per year dose limit for bystanders, operators, and other employees could potentially be exceeded only if an individual were to be present in the area 100% of the time for 2,000 hours (a typical work year) and 180 screenings per hour were performed. APL noted that this is a conservative calculation because it is based on the maximum measured dose of 1.6 μrem (.016 μSv) per screening at that location. This area begins approximately 9 feet above the floor and extends

vertically to a height of 14 feet and horizontally 4.6 feet behind each unit, as demonstrated in the figure below.

APL recommended conducting a survey of each installation site to ensure that the dose to any member of the general public is maintained below the 100 mrem (1 mSv) per year and to consider the installation of a beam stop for the area above the units.

Resolution: TSA's routine site acceptance test (SAT) for each installation includes a radiation safety survey. These surveys verify that the unit operates within specifications and are installed correctly and, therefore, the dose to any member of the general public, system operators, or other employees will always be less than 100 mrem (1 mSv) per year. In typical airport configurations, this area is normally unoccupied space between the unit and the ceiling. Additionally, any wall or floor between the individual and the Secure 1000 unit would provide adequate shielding to keep the radiation dose well below 100 mrem (1 mSv) per year.

Figure 1. Dose to General Public Above Units



During the design phase to date for installation of Rapiscan units, TSA has not encountered airports with an occupied space within the 9 to 14 feet zone. However, in the event that there is a balcony or similar structure without any walls or floors, TSA would comply with APL's recommendation to include a beam stop in the design. For sites where a beam stop would be required, TSA is working with Rapiscan to finalize a solution that can be installed on units on an as-needed basis to be determined by the site survey. Rapiscan has provided two beam stop design options for TSA's review as an additional precautionary measure.

- Recommendation: Site Surveys
  Status: Complete

  Issue: APL identified a second space at the entry and exit to the scan area where the annual general public dose limit could potentially be exceeded only if an individual were to be present in the area 100% of the time for 2,000 hours (a typical work year) and 180 screenings per hour were performed. The dose per scan measured was 0.84 μrem (0.0084 μSv). This area extends 1.7 feet from the sides of the units at the entry and exit locations. APL recommended that a survey of each installation site be conducted to ensure that the dose to any member of the general public is maintained below the annual limit of 100 mrem (1 mSv) and that doses are kept as low as reasonably achievable.

  Resolution: TSA requires two radiation safety checks, which are conducted prior to shipment from the manufacturer and upon delivery to the screening checkpoint site. Prior to shipment, Rapiscan conducts radiation validation tests on each unit in the factory during their quality assurance process, known as a factory acceptance test (FAT). TSA then conducts an independent site acceptance test (SAT), which includes a radiation safety survey for each system installation.

  APL employed the aforementioned conservative calculation, using the highest average dose measurement near the system. The average doses ranged from 0.07 μrem (0.0007 μSv) to 0.84 μrem (0.0084 μSv). Preliminary measurements made by the U.S. Army Public Health Command (Provisional) on production units have been consistent with the lower values reported by APL rather than the higher values. Based on the production unit measurements and the conservative calculation mentioned above, the dose to individuals at these locations would be well below the annual general public dose limit. Additionally, it is operationally not feasible for an individual to be in the space at the entry and exit to the scan area for 2000 hours in a year; therefore, there is no risk to passengers or employees.

- Recommendation: Emergency Stop Button
  Status: Complete

  Issue: APL noted that the Rapiscan Secure 1000 Single Pose system, which was provided for evaluation, was an engineering unit built by the Rapiscan engineering team using components from their inventory and configured to be the same version level and functionally equivalent to the system evaluated by the Department of Homeland Security (DHS) Transportation Security Laboratory (TSL). The emergency stop button on the

engineering unit provided for analysis was not wired. Therefore, functional performance could not be validated.

Resolution: Rapiscan reported that the unit provided to the Transportation Security Lab (TSL) incorporated an emergency stop button, which passed TSL's qualification process. All units installed at screening checkpoints are equipped with a functioning emergency stop on each unit.

- Recommendation: Radiation Label
  Status: Complete

  Issue: APL noted that, depending on the position of the generator, the radiation warning label on the X-ray tube may not be clearly visible and stated that "the label may need to be placed in a more visible location." APL also indicated that the shielding assembly did not have a warning label as required by ANSI/HPS-N43.17-2002, section 6.4, and ANSI/HPS N43.17-2009, section 7.3.

  Resolution: TSA is working with Rapiscan to ensure warning label visibility by increasing the number of labels found on the X-ray tubes. On December 2, 2009, as part of their Engineering Change Notice procedure, Rapiscan began including a warning label on the shielding assembly. The change is documented under ECN 03142.

- Recommendation: Single Pose Configuration Draft Operator Manual
  Status: Complete

  Issue: APL stated that the Secure 1000 in Single Pose Configuration draft Operator Manual and draft Maintenance Manual provided were under revision and that the final version of the documents should be reviewed.

  Resolution: TSA has provided final versions of these documents (Operator and Maintenance Manuals) to APL for review on June 21, 2010. These revisions were not identified as safety concerns.

- Recommendation: Revisions Required for Technique Factors and Additional Information
  Status: Complete

  Issue: APL noted that the draft Operator Manual, draft Maintenance Manual, and Specification Sheet provide the information required by ANSI/HPS N43.17-2002, sections 6.6 and ANSI/HPS N43.17-2009, sections 7.5 (b), (c), (d), (e), and (f) with the exception of technique factors (peak kilovoltage, electrical current, scan time) for each mode and total aluminum equivalent filtration. APL stated that the "final documents should be reviewed when completed and it is recommended that document revisions include information required for technique factors and additional information required by ANSI/HPS N43.17-2009, sections 7.5 (a), (g), (h), (i), and (j)."

Resolution: TSA provided final versions of these documents (e.g., operator manuals, specification sheet, and maintenance manuals) to APL for review on June 21, 2010.

- Recommendation: Documentation for Radiation Tests
  Status: Complete

  Issue: APL stated that "Rapiscan's Site Acceptance Test (SAT) provides functional system tests and a radiation survey that must be completed and approved for unit acceptance. Installation procedures were not provided. Since the system evaluated was installed by Rapiscan, requirements ANSI/HPS N43.17-2002, section 7.2, and ANSI/HPS N43.17-2009, section 8.1.2 were not evaluated."

  Resolution: Rapiscan verified that radiation tests are conducted during the production and installation of all AIT systems. The documentation for each test is on file at Rapiscan. However, the test was not originally listed in the factory acceptance test (FAT) or SAT documentation. Rapiscan has since revised the FAT and SAT reports to document when a test is successfully completed. Once submitted and approved, it will be documented in the SAT report moving forward.

- Recommendation: FDA Filing for the Secure 1000 Unit
  Status: Complete

  Issue: APL remarked that the existing Rapiscan Food and Drug Administration (FDA) filing is for the Secure 1000 unit, dated 1992. The Secure 1000 in Single Pose Configuration is configured differently than Secure 1000 from the filing; however, there is no filing for the new configuration.

  Resolution: Rapiscan has updated its FDA filing to include the Single Pose system. This filing is under Accession Number RH1080004 and RH1080004-001.