Radiation Safety Engineering Assessment Report for the Rapiscan Secure 1000 in Single Pose Configuration

VERSION 2.0

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Radiation Safety Engineering Assessment Report for the Rapiscan Secure 1000 in Single Pose Configuration

Executive Summary

The Johns Hopkins University Applied Physics Laboratory (JHU/APL) is providing technical support to the United States (U.S.) Department of Homeland Security (DHS) Transportation Security Administration (TSA) in evaluating X-ray systems used for screening vehicles and personnel. TSA directed JHU/APL to conduct an independent radiation safety engineering assessment of the Rapiscan Secure 1000 in Single Pose Configuration. The objectives of the assessment were to measure, verify, and report the parameters of system performance against TSA requirements, ANSI/HPS N43.17-2002, ANSI/HPS N43.17- 2009, and C.F.R. Title 21 Chapter I Subchapter J Part 1002 Records and Reports. When the radiation safety engineering assessment was conducted in July 2009, the ANSI/HPS N43.17-2002 standard was in effect, but the revised standard ANSI/HPS N43.17-2009 was voted on and approved by the ANSI/HPS N43.17 Standards Subcommittee and awaiting formal approval and publication by ANSI. For completeness, this report presents findings of the assessment against both ANSI/HPS N43.17-2002 and ANSI/HPS N43.17-2009 in relevant areas. Dose to scanned individuals and Negligible Individual Dose (NID) for the two standards reported in this document differ due to the methods of calculation required by each standard.

The Rapiscan Secure 1000 in Single Pose Configuration is a two-sided X-ray backscatter Whole Body Imager that can be used to detect objects concealed under a person's clothing. The single pose configuration consists of two Rapiscan Secure 1000 units (master and slave) placed facing each other that are controlled and operated through a common operator's console. The single pose configuration is achieved by the master unit scanning the front view and the slave unit scanning the back view of the subject instead of requiring the subject to pose twice for a front and back scan. To be scanned, the subject enters the inspection aisle of the Secure 1000 in Single Pose Configuration, faces the master unit and stands still. The subject's front and back sides are then scanned sequentially by the master and slave units in an automated manner with just one pose.

The radiation safety engineering assessment of the Rapiscan Secure 1000 in Single Pose Configuration included a review of prior third party radiation testing and detailed radiation safety testing conducted at Rapiscan's facility in Torrance, California from July 27 – 29, 2009. The results of the assessment are as follows:

- The system provided for radiation safety evaluation was an engineering unit built by the Rapiscan engineering team using components from their inventory and configured to be at the same version level and functionally equivalent to the system evaluated at the Transportation Security Laboratory (TSL).
- Performance differences were noted between the master and slave engineering units that may not appear in production systems that are subject to the quality control (QC) process. Where differences were noted the most conservative measurements were used.

- The dose to scanned individuals is within the requirements of ANSI/HPS N43.17-2002, 5.1:
  - Individual effective dose per screening (frontal and rear scan) of a subject is 1.55 μrem (0.0155 μSv), less than the 10 μrem (0.10 μSv) limit.
  - Individual effective dose is below 25 mrem if an individual is subject to fewer than 16,129 screenings in a twelve-month period (equivalent to 44 screenings per day, 365 days per year).
- The dose to scanned individuals is within the requirements of ANSI/HPS N43.17-2009, 6.1.1.1:
  - The average effective dose per screening (frontal and rear scan) of a subject is 1.46 μrem (0.0146 μSv), less than the 25 μrem (0.25 mSv) per screening limit.
  - Individual effective dose is below 25 mrem if an individual is subject to fewer than 17,123 screenings in a twelve-month period (equivalent to 46 screenings per day, 365 days per year).
- Individual effective dose is below Negligible Individual Dose (NID) (per ANSI/HPS N43.17-2002 5.3 and 2009 B.4) of 1 mrem (0.01 mSv) per year if an individual is subjected to:
  - fewer than 645 screenings in a year (based on 1.55 μrem/screening for N43.17-2002) or
  - fewer than 684 screenings in a year (based on 1.46 μrem /screening for N43.17-2009).
- The aluminum-equivalent total filtration is within the requirements of ANSI/HPS N43.17-2009, 7.1:
  - The X-ray beam is attenuated by approximately 1.18 mm of aluminum-equivalent total filtration for the master unit and 1.63 mm of aluminum-equivalent total filtration for the slave unit, greater than the minimum requirement of no less than 1 mm of aluminum-equivalent total filtration.
- **Additional action is recommended** to ensure that the National Council on Radiation Protection and Measurements (NCRP 1993) general public dose recommendation of less than 100 mrem (0.1 rem) per year is being met (ANSI/HPS N43.17-2002, 5.3 and ANSI/HPS N43.17-2009, B.4). Specifically:
  - An area exists above each of the units, due to primary beam overshoot, where the 100 mrem per year general public dose limit could potentially be exceeded. This area extends up to a height of about 14 ft and 4.6 ft behind each of the units.
  - A second area exists at the entry and exit locations of the scan area, where the 100 mrem per year general public dose limit could potentially be exceeded. This area extends approximately 1.7 ft from the side of the units at the entry and exit locations.

  - It is 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 100 mrem (0.1 rem) per year general public limit and to ensure that doses are kept "As Low As Reasonably Achievable" (ALARA).
  - For the area above the units, a beam stop may be considered to ensure the general public dose is maintained.
- The dose to bystanders is within the requirements of ANSI/HPS N43.17-2002, 5.4 and ANSI/HPS N43.17-2009, 6.2:
  - Dose to bystanders is less than 2 mrem in any one hour period, varying from 0.043 to 0.704 mrem at a very conservative 100% duty and 100% occupancy and 0.003 to 0.053 mrem with a 30% duty factor and 25% occupancy factor applied.
- The dose to workers is within the requirements of ANSI/HPS N43.17-2002, 5.4 and ANSI/HPS N43.17-2009, 6.2:
  - Dose to personnel at any Secure 1000 in Single Pose Configuration workstation is below 100 mrem/year (or 50 µrem/hour) when there are fewer than 238 screenings/hour (assuming 50 weeks per year, 40 hours per week, 8 hours per day).
- The system meets the shielding requirements of ANSI/HPS N43.17-2002, 5.5 and ANSI/HPS N43.17-2009, 6.3:
  - Leakage dose rate at 30 cm from any external surface of the master and slave unit are not distinguishable from background exposure.
- The system provides necessary indicators and controls, access panel interlocks, and operational interlocks required by ANSI/HPS N43.17-2002, 6.1, 6.2.1, 6.2.2, ANSI/HPS N43.17-2009, 7.2.1 (a), (b), (c), (d), (e), (i), (l), (m), (n), 7.2.2 (b), (c), and TSA to prevent unauthorized system access, conduct safe operation, and provide an emergency stop capability.
- Depending on the position of the generator, the radiation warning label on the X-ray tube may not be clearly visible. The label may need to be placed in a more visible location. The shielding assembly does not have a warning label as required by ANSI/HPS-N43.17-2002, 6.4 and ANSI/HPS N43.17-2009, 7.3.
- The draft Operator Manual, draft Maintenance Manual, and Specification Sheet provide the information required by ANSI/HPS N43.17-2002, 6.6 and ANSI/HPS N43.17-2009 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. 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, 7.5 (a), (g), (h), (i), and (j).
- Rapiscan's Site Acceptance Test (SAT) provides functional system tests and a radiation survey that must be completed and approved for system acceptance. Installation procedures were not provided. Since the system evaluated was installed by Rapiscan,

requirements ANSI/HPS N43.17-2002, 7.2 and ANSI/HPS N43.17-2009, 8.1.2 were not evaluated.

- A Radiation Safety Product report filing is required by FDA C.F.R. 21 Subchapter J Part 1002, ANSI/HPS N43.17-2002 4, and ANSI/HPS N43.17-2009 4. The existing Rapiscan FDA filing is for the Secure 1000 system, 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. The FDA responded to the 1992 filing stating *"...this product is not actively regulated under the device authorities of the Food Drug and Cosmetic Act (FFDCA). The Performance Standard for Diagnostic X-Ray Systems and Their Major Components does not apply to the Secure 1000."*

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Version Control: Radiation Safety Engineering Assessment Report for the Secure 1000 in Single Pose Configuration

Date	Description	Version
10/30/2009	Baseline Version Release	1.0
08/30/2010	Updates per Summary of Changes on pages ix and x.	2.0

Summary of Changes to Radiation Safety Engineering Assessment Report for the Secure 1000 in Single Pose Configuration, Version 2.0

Section	Change
Page ii	Removed Program Manager name and contact information. Removed author names.
Executive Summary Section 8.3, Assessment Results Section 8.3, Page 14, 1st Paragraph	As a result of a transcription error in Tables 8-3 and 8-4, where background exposure was corrected from 0.0006 μR to 0.06 μR, the following changes were made to the section, where applicable, to reflect this correction: For ANSI/HPS N43.17-2002, 5.1: - Effective dose per scan for the front of the subject was changed from "1.10 μrem (0.011 μSv)" to "1.08 μrem (0.0108 μSv)". - Effective dose per screening (frontal and rear scan) was changed from "1.58 μrem (0.0158 μSv)" to "1.55 μrem (0.0155 μSv)". - Effective dose is below 25 mrem was changed from "15,822" to "16,129" screenings in a twelve-month period and from "43" to "44" screenings per day.
Executive Summary Section 8.4, Assessment Results and Page 15, 3rd Paragraph	As a result of a transcription error in Tables 8-3 and 8-4, where background exposure was corrected from 0.0006 μR to 0.06 μR, the following changes were made to reflect this correction: For ANSI/HPS N43.17-2009, 6.1.1.1: - The average effective dose per screening (frontal and rear scan) of a subject changed from "1.48 μrem (0.0148 μSv)" to "1.46 μrem (0.0146 μSv)". - Individual effective dose is below 25 mrem was changed from "16,891" to "17,123" screenings in a twelve-month period.
Executive Summary Section 8.5, Assessment Results	As a result of a transcription error in Tables 8-3 and 8-4, where background exposure was corrected from 0.0006 μR to 0.06 μR, the following changes were made to reflect this correction: Negligible Individual Dose (NID) for ANSI/HPS N43.17-2002 was changed from "632" to "645" screenings in a year based on change from "1.58" to "1.55" μrem/screening. NID for ANSI/HPS N43.17-2009 was changed from "675" to "684" screenings in a year based on change from "1.48" to "1.46" μrem/screening.
Section 8.3, Figure 8-4	As a result of a typographical error, the following text in the legend was changed in Figure 8-4: "4.71" changed to "4.574" μrem for Master Unit "4.68" changed to " 4.606" μrem for Slave Unit
Section 8.3, Table 8-3	As a result of a transcription error in Tables 8-3 and 8-4, where background exposure was corrected from 0.0006 μR to 0.06 μR, the following changes were made in Table 8-3 to reflect this correction:

Section	Change
	For Master Unit Frontal Scan, Average Exposure per Scan (μR/scan) was changed from "4.77" to "4.71" and Effective Dose per Scan (μrem/scan) was changed from "1.1" to "1.08". For Slave Unit Rear Scan, Average Exposure per Scan (μR/scan) changed from "4.8" to "4.74" and Effective Dose per Scan (μrem/scan) was changed from "0.48" to "0.47". For Master + Slave Unit, Average Exposure per Screening (μR/screening) was changed from "9.57" to "9.45" and Effective Dose per Screening (μrem/screening) was changed from "1.58" to "1.55". In Note 3, "0.0006" was changed to "0.06" μR.
Section 8.4, Table 8-4	As a result of a transcription error in Tables 8-3 and 8-4, where background exposure was corrected from 0.0006 μR to 0.06 μR, the following changes were made in Table 8-4 to reflect this correction: For Master Unit, Average Exposure per Scan (μR/scan) was changed from "4.77" to "4.71" and Effective Dose per Scan (μrem/scan) was changed from "0.62" to "0.61". For Slave Unit, Average Exposure per Scan (μR/scan) was changed from "4.80" to "4.74" and Effective Dose per Scan (μrem/scan) was changed from "0.86" to 0.85". For Master + Slave Unit, Average Exposure per Screening (μR/screening) was changed from "9.57" to "9.45" and Effective Dose per Screening (μrem/screening) was changed from "1.48" to "1.46".
Section 8.6.1, Table 8-8	As a result of a typographical error for Background Reading Ion Chamber heading column, "mR" was changed to "μR". As a result of a transcription error in Table 8-8 where background reading for Location 11 at 99.5 inch height was corrected from 0.09 μR to 0.10 μR, the following changes were made to Location 11 at 99.5 inch height to reflect this correction: Background Reading Ion Chamber (μR) changed from "0.09" to "0.10". Average Exposure with Background Subtracted (μR/screening) changed from "0.85" to "0.84". Average Exposure with Background Subtracted and Energy Correction Applied (μR/screening) changed from "0.87" to "0.85".
Section 8.6.3, Page 29, 2nd Paragraph	Due to Table 8-8 changes noted above, "0.519" mrem changed to "0.512" mrem and "0.039" mrem changed to "0.038" mrem.
Section 8.6.3, Table 8-9	Due to Table 8-8 changes noted above, the following changes were made for Table 8-9, Location 11: Average Background Reading (μR) changed from "0.09" to "0.10". Average Exposure with Background Subtracted and Energy Correction Applied (μR/screening) changed from "0.865" to "0.853".

Section	Change
	Equivalent Dose for 100% Duty and 100% Occupancy (mrem in any 1 hour) changed from "0.519" to "0.512". Equivalent Dose (mrem/screening x D x T) (mrem in any 1 hour) changed from "0.039" to "0.038".
Section 8.2 and References	Author's names were removed.

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1. BACKGROUND

The Johns Hopkins University Applied Physics Laboratory (JHU/APL) is providing technical support to the United States (U.S.) Department of Homeland Security (DHS) Transportation Security Administration (TSA) in evaluating X-ray systems used for screening vehicles and personnel. TSA directed JHU/APL to conduct an independent radiation safety engineering assessment of the Rapiscan Secure 1000 in Single Pose Configuration.

2. PURPOSE

This report summarizes the radiation safety engineering assessment findings for the Secure 1000 in Single Pose Configuration. Test objectives, assumptions and constraints, system description, instrumentation, applicable standards, and radiation safety engineering assessment analysis and findings are provided.

3. TEST OBJECTIVES

The objectives of the radiation safety engineering assessment of the Secure 1000 in Single Pose Configuration were to measure, verify, and report the parameters of system performance against TSA requirements, ANSI/HPS N43.17-2002 (Reference [1]), ANSI/HPS N43.17- 2009 (Reference [2]), and C.F.R. Title 21 Chapter I Subchapter J Part 1002 Records and Reports (Reference [3]).

4. ASSUMPTIONS AND CONSTRAINTS

This section describes key assumptions, constraints, risks and risk mitigations.

4.1 Assumptions

The key assumptions made for this evaluation were that the vendor would provide a complete set of technical details and documentation as requested and that the system would be available in a timely manner. All requested documentation and information was provided to JHU/APL at the California (CA) site. The system was available for three days of testing and Rapiscan engineers were available at all times during the test period to ensure that all testing was completed.

4.2 Constraints

The radiation safety evaluation was conducted at the vendor site using a configuration comprised of two Secure 1000 engineering units dated 2005 and 2007. The Secure 1000 in Single Pose Configuration provided for evaluation was built by the Rapiscan engineering team using components from their inventory and was configured to be at the same version level and functionally equivalent to the system evaluated at the Transportation Security Laboratory (TSL).

The preferred location for testing would have been at JHU/APL using a Secure 1000 in Single Pose Configuration system that passed Rapiscan production and quality control checks to ensure consistency of performance and integrity of the system. However, a spare system was not available to facilitate this.

4.3 Risks and Risk Mitigation

The successful implementation and execution of the radiation safety engineering assessment depended on conditions and events that have inherent risks associated with them. This section describes the identified key risks, planned risk mitigation, and any risk mitigation actions taken.

Risk: The system evaluated may be configured differently than the system deployed to the operational environment.

Planned Risk Mitigation: Through the review of documentation, JHU/APL will verify that the radiation safety evaluation conducted is sufficient to ensure compliance with requirements, standards, and regulations. If needed, additional testing will be conducted.

Mitigation Action: The system evaluated was an engineering system and performance differences were noted between the master and slave units. It is assumed that production units that are subjected to the quality control (QC) process would provide equal performance or better, therefore, the assessment conducted is considered sufficient. However, radiation surveys should be conducted for each installation site as required and it should be verified that the differences in performance observed in the engineering unit are not observed in production units.

Risk: It may not be possible to take measurements due to the system configuration or other physical constraints.

Mitigation: JHU/APL will use the best information available and analytical engineering practices to address the situation.

Mitigation Action: Rapiscan engineers supported the radiation safety testing and provided all necessary configuration changes required to conduct a complete assessment.

5. SYSTEM DESCRIPTION

The Rapiscan Secure 1000 in Single Pose Configuration is a two-sided X-ray backscatter Whole Body Imager that can be used to detect objects concealed under a person's clothing. The single pose configuration consists of two Rapiscan Secure 1000 units (master and slave) placed facing each other that are controlled and operated through a common operator's console. The single pose configuration is achieved by the master unit scanning the front view and the slave unit scanning the back view of the subject instead of requiring the subject to pose twice for a front and back scan. To be scanned, the subject enters the [redacted] inspection aisle of the Secure 1000 in Single Pose Configuration, faces the master unit, and stands still. The subject's front and back sides are then scanned sequentially by the master and slave units in an automated

5 USC 552(b)(4)

manner with just one pose. The master and slave units of the Secure 1000 in Single Pose Configuration are of identical construction and generate an X-ray image by scanning in both the horizontal and the vertical direction, on each side of the system. [redacted] According to the vendor, exposure to the subject screened by the Secure 1000 in Single Pose Configuration is less than 10 μrem per scan, and the scan rate for both scans is approximately 6 seconds. After the subject is scanned, the front and back views are displayed on the operator's console on a high-resolution color monitor.

5 USC 552(b)(4)

[redacted] Figures 5-1, [redacted]

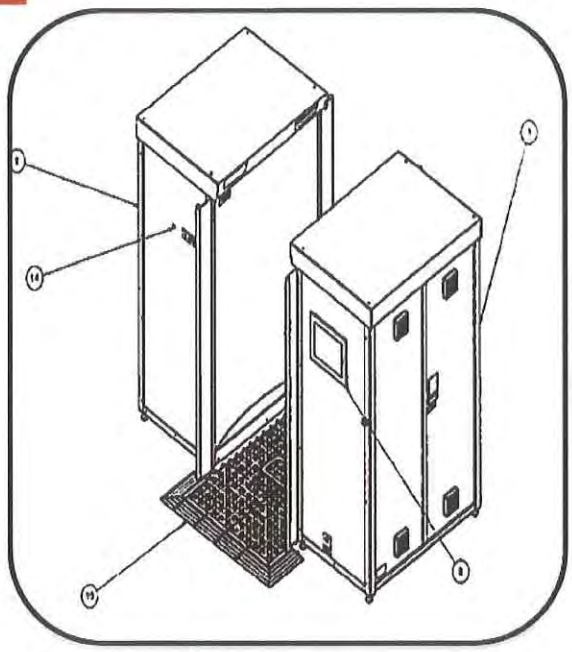
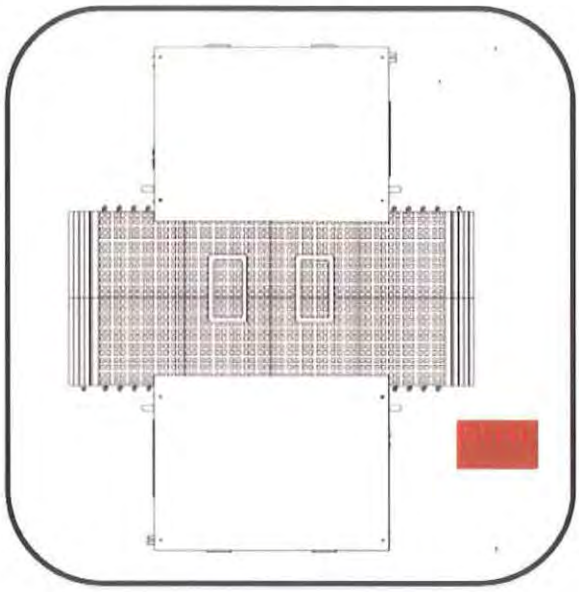


Figure 5-1. 3-D View of the Secure 1000 in Single Pose Configuration (Reference [4])



5 USC 552(b)(4)

Figure 5-2. Top View of the Secure 1000 in Single Pose Configuration (Reference [4])

Note: The wings are not shown in this figure.

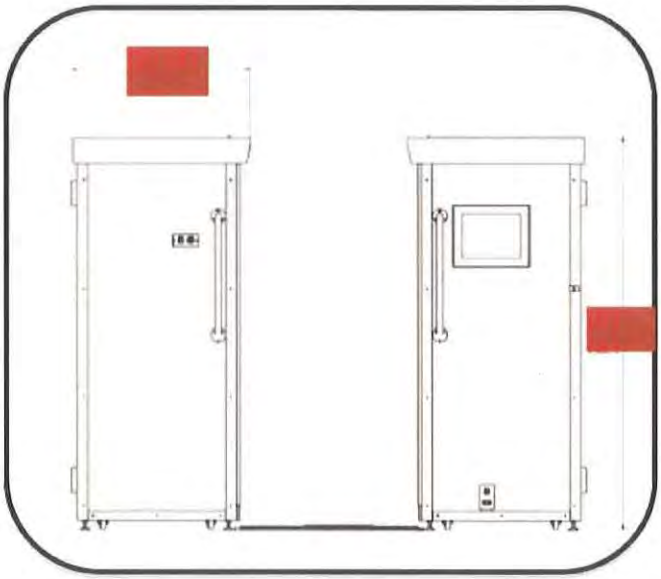


Figure 5-3. Side View of the Secure 1000 in Single Pose Configuration (Reference [4])

Note: The wings are not shown in this figure.

5 USC 552(b)(4)

Figure 5-4. Back View of One X-Ray Cabinet of the Secure 1000 in Single Pose Configuration (Reference [4])

Note: The wings are not shown in this figure.

6. INSTRUMENTATION

The radiation instruments used to conduct the radiation safety engineering assessment of the Secure 1000 in Single Pose Configuration are provided in Table 1. All radiation-measuring instruments used during the assessment are calibrated traceable to National Institute of Standards and Technology (NIST) standards.

Table 6-1. Instruments

Instrument/Equipment	Purpose
Radcal Corp 1800 Ion Chamber coupled to a Radcal Model 9010 Controller Instrument	Used for precise readings of radiation exposure in units of Roentgen (R). Calibration date: 7 July 2009.
Thermo Electron Corp. Micro Rem Radiation Survey Meter	Used for comparable dose measurement in units of Roentgen Equivalent Man (rem). Calibration date: 19 May 2009.
Ludlum Measurements Inc. Model 3 Survey Meter coupled either to a Ludlum Model 44-9 Pancake Geiger-Mueller (Pan-GM) Probe or a Ludlum Model 44-3 Thin Crystal Sodium Iodide (NaI) Scintillator Probe	Used during the area survey to identify the area with the highest radiation readings in terms of counts per minute (cpm). Calibration date: 30 June 2009.
Radcal Rapidose (with tripod)	Used for kVp measurement. Calibration date: 24 June 2009.

7. APPLICABLE STANDARDS

The radiation safety engineering assessment was conducted to verify conformance with the ANSI and FDA standards and regulations listed below.

- ANSI/HPS N43.17-2002, American National Standard Radiation Safety for Personnel Screening Systems Using X-rays (Reference [1])
- ANSI/HPS N43.17- 2009 Final for Publication, American National Standard Radiation Safety for Personnel Screening Systems Using X-ray or Gamma Radiation (Reference [2])
- U.S. Food and Drug Administration Title 21, Volume 8, Chapter I Food and Drug Administration Department of Health and Human Services, Subchapter J Radiological Health, Part 1002 Records and Reports (Reference [3])

When the radiation safety engineering assessment was conducted in July 2009, the ANSI/HPS N43.17-2002 standard was in effect, but the revised standard ANSI/HPS N43.17-2009 was voted on and approved by the ANSI/HPS N43.17 Standards Subcommittee and awaiting formal approval and publication by ANSI. For completeness, this report presents findings of the assessment against both ANSI/HPS N43.17-2002 and ANSI/HPS N43.17-2009 in relevant areas. Dose to scanned individuals and Negligible Individual Dose (NID) for the two standards reported in this document differ due to the methods of calculation required by each standard.

8. RADIATION SAFETY ENGINEERING ASSESSMENT FINDINGS

The radiation safety engineering assessment of the Rapiscan Secure 1000 in Single Pose Configuration included a review of prior third party radiation testing and detailed radiation safety testing conducted at Rapiscan's facility in Torrance, California from July 27 – 29, 2009. The results of the assessment include findings for the following: system configuration, third party radiation testing, dose to scanned individuals, negligible individual dose, dose to general public, dose to bystanders, dose to workers, leakage dose rate, and physical safety. The following sections provide details of the assessment.

8.1 Configuration of System Evaluated

Images of the Secure 1000 in Single Pose Configuration as configured during JHU/APL testing are provided in Figure 8-1. Prior to conducting the testing, Rapiscan provided a configuration list (reference Appendix A for the configuration list) and identified the following differences between the configuration of the Torrance, CA system evaluated by JHU/APL and the systems undergoing qualification testing at the TSL:

- The LCD monitor of the TSL system is older (Rev 2) than the monitor of the CA system (Rev 4).
- The TSL system has a monitor for both sides of the system, where the CA system only has a monitor for the master side of the system.
- The power driver board of the TSL system is older [redacted] than the power driver board of the CA System [redacted]
- The software of the TSL system is older [redacted] than the software of the CA system [redacted] Rapiscan reported that there were no software changes that impact X-ray generation or radiation safety.

5 USC 552(b)(4)

JHU/APL conducted an audit of the system configuration at the Torrance, CA test site, additional differences identified were as follows:

- The system provided for radiation safety evaluation was an engineering unit built by the Rapiscan engineering team using components from their inventory and configured to be at the same version level and functionally equivalent to the system evaluated at the TSL.
- Since the CA system is an engineering unit,
  - the components were not subject to the QC process used for production units,
  - the master unit was dated 2007 and the slave unit was dated 2005, and
  - the slave unit X-ray generator tube was of a previous generation.
- At the beginning of radiation safety testing, the X-ray generator in the master unit was replaced due to a damaged high voltage (HV) power supply.
- Performance differences were noted between the master and slave engineering units that may not appear in production systems that are subject to the QC process. Where differences were noted, the most conservative measurements were used.
- Many of the part number labels did not match the part numbers on the configuration list, Rapiscan indicated that they did not maintain the part number labels on the engineering system.
- The engineering system did not implement the emergency stop capability. The slave unit had an emergency stop button, however the button connections were not wired to the system and the button was not operable. The master unit did not have an emergency stop button.

Figure 8-1. Secure 1000 in the Single Pose Configuration Torrance, CA

8.2 Assessment of Prior Third Party Radiation Testing

Medical and Health Physics Consulting conducted radiation assessments to verify that the system was in compliance with requirements stated in ANSI/HPS N43.17-2002; 5.1, 5.4, and 5.5. The reports for these assessments are dated March 21, 2006 (Reference [5]), June 5, 2008 (Reference [6]), and October 28, 2008 (Reference [7]). An additional assessment was conducted by National Institute of Standards and Technology (NIST) with report dated July 9, 2008 (Reference [8]). Findings from the review of the above reports are as follows:

- The Medical and Health Physics Consulting assessment was conducted for compliance with ANSI/HPS N43.17-2002 5.1 Subject Dose Limitation, 5.4 Dose to Bystanders and 5.5 Shielding. Although the reports indicate compliance with sections 5.1, 5.4 and 5.5, the following points should be considered:
  - The reports do not indicate that an X-ray scattering source was used to determine dose to bystanders.
  - A complete area survey was not conducted with the new configuration of two units facing each other to determine exposure to bystanders and operators.
  - A complete radiation leakage survey at 30 cm from all surfaces was not conducted with the new configuration of two units facing each other.
  - Readings were taken with one active X-ray unit. The second X-ray unit was deactivated. Exposure from both active units should be measured and reported.
  - The evaluation does not assess compliance with other ANSI/HPS N43.17 requirements such as indicators, controls, keys and safety interlocks.
- The NIST report provides an assessment based on a review of the Medical and Health Physics Consulting report dated June 5, 2008 and indicates that the Rapiscan Dual Secure 1000 conforms to dose limitation requirements of ANSI/HPS N43.17-2002. The following observations were highlighted in the report:
  - Noted that the second X-ray unit was deactivated.
  - Noted that no data was received regarding radiation scattered from the screened individuals into adjacent areas.
  - Noted that based on the size of the ion chamber used by Medical and Health Physics Consulting, it is uncertain whether the shield intercepted the entire beam.
  - Recommended that "Exposure measurements should be made at the back of each unit while the opposite unit is scanning to verify proper shielding of the primary beam". Medical and Health Physics Consulting took measurements on the back of one inactive unit in a follow up report.
  - Noted that there was a design change to the curvature of the front panel of the Secure 1000 since the Medical and Health Physics Consulting test.

8.3 Dose to Scanned Individuals for ANSI/HPS N43.17-2002

Standard:

- The effective dose shall not exceed 10 μrem (0.10 μSv) per scan of the subject's front. (ANSI/HPS N43.17-2002, 5.1 Subject Dose Limitations)

- The facility shall be operated to ensure that no individual scanned receives from the facility an effective dose in excess of 25 mrem (0.25 mSv) in any twelve-month period. (ANSI/HPS N43.17-2002, 5.1 Subject Dose Limitations)
- The x-ray beam shall be attenuated by no less than 1 mm of aluminum-equivalent total filtration before exiting the beam exit surface. (ANSI/HPS N43.17-2009, 7.1 Filtration)

Assessment Results:

- The average effective dose per scan for the front of a subject is 1.08 μrem (0.0108 μSv).
- The average effective dose per screening (frontal and rear scan) of a subject is 1.55 μrem (0.0155 μSv).
- Individual effective dose is below 25 mrem if individual is subject to less than 16,129 screenings in a twelve-month period which is equivalent to 44 screenings per day (365 days per year).
- The X-ray beam is attenuated by approximately 1.18 mm of aluminum-equivalent total filtration for the master unit and 1.63 mm of aluminum-equivalent total filtration for the slave unit.
- The operating potential of the master and slave unit is 50 kV [redacted] 5 USC 552(b)(4)

To determine subject effective dose, readings were made with one unit at a time to understand the subject dose from a single unit. For these measurements, Rapiscan engineers used a special "servicing mode" to disable one unit and conduct operational scans with the other unit. When used in the operational mode, the Single Pose system X-ray scan is less than 6 seconds in duration (less than 3 seconds for the master unit and less than 3 seconds for the slave unit); therefore 3-second scans for a single unit were used for the measurements. To support the subject effective dose measurement, readings were conducted for half value layer (HVL), kVp, and subject dose at 30 centimeters from the exit panel.

To determine the HVL, the following was conducted for each unit (master and slave):

- Using servicing mode, Rapiscan engineers disabled one unit and configured the other unit for the operational parameters of 50 kV, [redacted]
- The ion chamber was placed in front of a unit and centered at the location where the X-ray beam passed during a scan, as shown in Figure 8-2. To shield the ion chamber from extraneous radiation within the Rapiscan facility, a piece of lead was placed on top of the chamber and bent to form around the chamber, as seen in Figure 8-3.
- Five 3-second scans with a single unit were conducted with 0 mm Al to determine the unfiltered initial exposure.
- Five 3-second scans with a single unit were conducted with 0.51 mm Al, as shown in Figure 8-3. This was repeated for 1.02 mm Al, 2.04 mm Al, and 3.06 mm Al when the half value of the initial exposure was obtained.

The X-ray beam is attenuated by approximately 1.18 mm of aluminum-equivalent total filtration for the master unit and 1.63 mm of aluminum-equivalent total filtration for the slave unit. Table 8-1 provides the data for the master unit and Table 8-2 provides the data for the slave unit. Figure 8-4 shows the filtered exposure readings and HVL.

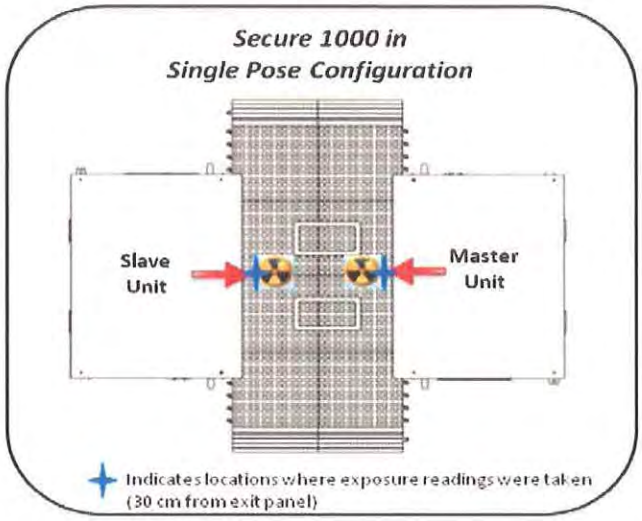


Figure 8-2. Ion Chamber Location for Exposure Readings

Figure 8-3. Ion Chamber Configuration for HVL Readings

Table 8-1. Master Unit HVL Data

Master Unit					
Scan Number	**Exposure Reading for 0 mm Al (μR)[1]**	**Exposure Reading for 0.51 mm Al (μR)[1]**	**Exposure Reading for 1.02 mm Al (μR)[1]**	**Exposure Reading for 2.04 mm Al (μR)[1]**	**Exposure Reading for 3.06 mm Al (μR)[1]**
1	4.58	3.17	2.39	1.62	1.06
2	4.5	3.17	2.46	1.62	1.06
3	4.64	3.17	2.39	1.62	1.06
4	4.57	3.1	2.46	1.62	1.06
5	4.58	3.17	2.46	1.62	1.06
Average	**4.574**	**3.156**	**2.432**	**1.62**	**1.06**
Average/2	**2.287**	HVL (mm Al) = 1.18			
COV	0.011	0.010	0.016	0.000	0.000

1. Master unit scan for total scan time of 3 seconds.

Table 8-2. Slave Unit HVL Data

Slave Unit					
Scan Number	**Exposure Reading for 0 mm Al (μR)[1]**	**Exposure Reading for 0.51 mm Al (μR)[1]**	**Exposure Reading for 1.02 mm Al (μR)[1]**	**Exposure Reading for 2.04 mm Al (μR)[1]**	**Exposure Reading for 3.06 mm Al (μR)[1]**
1	4.58	3.45	2.82	2.04	1.48
2	4.64	3.38	2.75	1.97	1.41
3	4.58	3.45	2.82	1.97	1.41
4	4.65	3.38	2.82	1.97	1.41
5	4.58	3.38	2.75	2.04	1.41
Average	**4.606**	**3.408**	**2.792**	**1.998**	**1.424**
Average/2	**2.303**	HVL (mm Al) = 1.63			
COV	0.008	0.011	0.014	0.019	0.022

1. Slave unit scan for total scan time of 3 seconds.

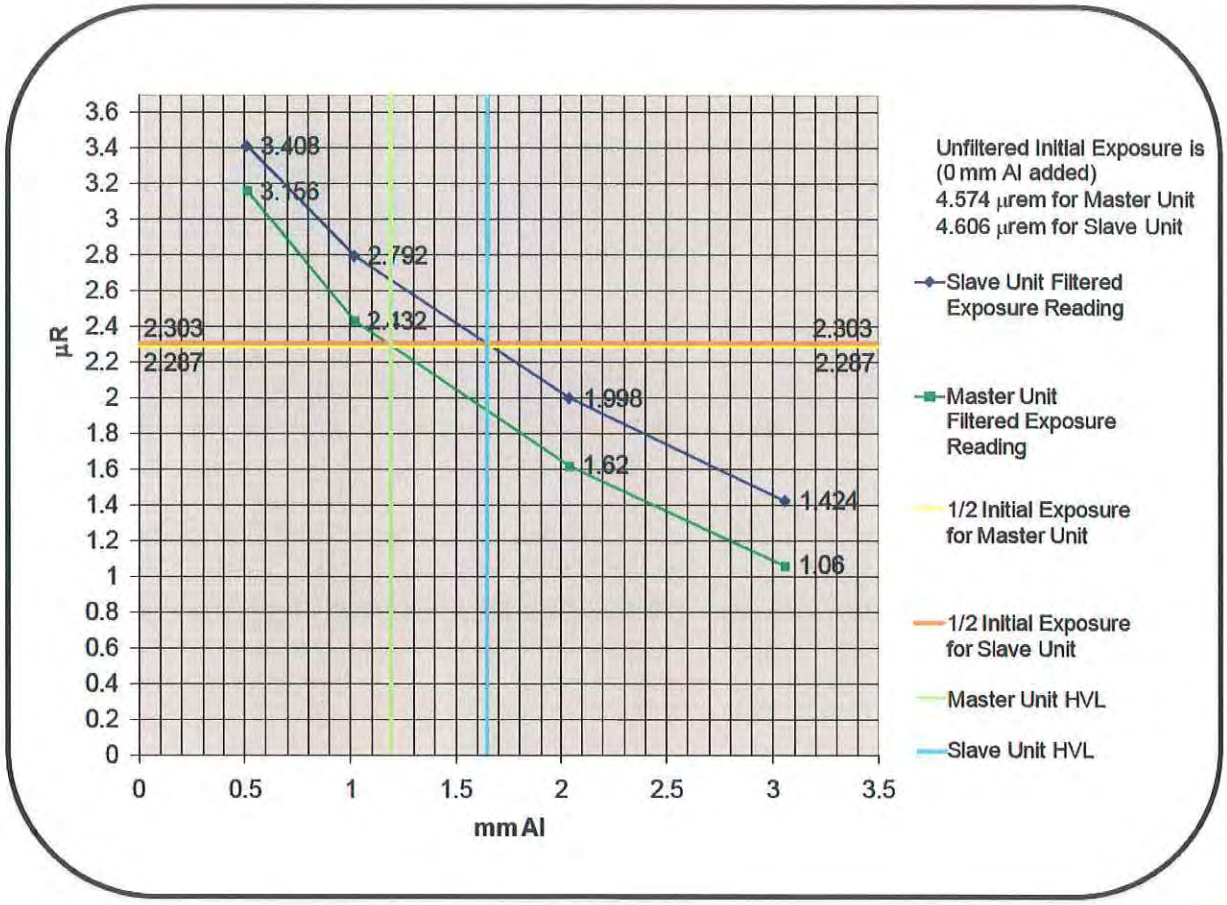


Figure 8-4. Filtered Exposure Readings and HVL

5 USC 552(b)(4)

To obtain kVp measurements, the Rapidose kVp meter was placed in front of the X-ray beam as shown in Figure 8-5. Rapiscan engineers used servicing mode to configure the system for 50 kV, [redacted] and operational 3-second scans. Multiple readings were conducted for both units. Due to the minimum beam hardness (2 mm Al) specified for the Rapidose kVp meter, the measurements of kVp made may not be accurate within +/- 5%. The indicated operating potential on both the master and slave units was 50 kV and the measurements made with the Rapidose (although not verified to required accuracy) indicate that the operating potential of the units does not exceed 50 kV. Therefore, as a conservative measure, the dose conversion coefficients are selected based on 50 kV.

Figure 8-5. Rapidose kVp Meter Configuration

Subject effective dose per scan for the front of a subject is 1.08 μrem (0.0108 μSv) and total subject effective dose per screening (frontal and rear scan) of a subject is 1.55 μrem (0.0155 μSv), as provided in Table 8-3. These measurements are based on the exposure readings noted in Table 8-3 and the HVL and kVp data provided in the above tables and figures. For the exposure readings, the ion chamber was placed 30 cm from the beam exit panel at a height of approximately 3 feet from the ground. The ion chamber was positioned so that the barrel was parallel to the exit panel. The results provided are for the maximum dose derived from a master frontal scan at 30 cm from the master beam exit panel and slave rear scan at 30 cm from the slave beam exit panel. Since the distance between these two points in the scan area is approximately 18.4 inches; it is conceivable that a scanned individual could be exposed to a consecutive master and slave scan at these locations.

Dose to scanned individuals for the two standards reported in this document differ due to the methods of calculation required by each standard.

Table 8-3. Subject Effective Dose per Scan and per Screening

	Average Exposure per Scan[3] (μR/scan)[4]	HVL	kVp[5]	Dose Conversion Coefficient[6]	Effective Dose per Scan (μrem/scan)
Master Unit Frontal Scan[1] at 30 cm from Master Unit Beam Exit Panel	4.71	1.18 mm Al	50	Front 0.23	1.08
Slave Unit Rear Scan[2] at 30 cm from Slave Unit Beam Exit Panel	4.74	1.63 mm Al	50	Rear 0.1	0.47

	Average Exposure per Screening[3] (μR/screening)[4]				Effective Dose per Screening (μrem/screening)
Master + Slave Unit (Frontal + Rear Scan)	9.45				1.55

1. Master unit scan for total scan time of approximately 3 seconds. Data for scans is as follows: Scan 1 – 4.72 μR, Scan 2 – 4.65 μR, Scan 3 – 4.65 μR, Scan 4 – 4.72 μR, Scan 5 – 4.65 μR.
2. Slave unit scan for total scan time of approximately 3 seconds. Data for scans is as follows: Scan 1 – 4.65 μR, Scan 2 – 4.8 μR, Scan 3 – 4.65 μR, Scan 4 – 4.73 μR, Scan 5 – 4.72 μR.
3. Background exposure 0.06 μR subtracted and energy correction factor 1.02 applied.
4. Results provided above are for the maximum dose derived from a master frontal scan and slave rear scan.
5. Due to the minimum beam hardness (2 mm Al) specified for the Rapidose kVp meter, the measurements of kVp made may not be accurate within +/- 5%. The indicated operating potential on both the master and slave units was 50 kV and the measurements made with the Rapidose (although not verified to required accuracy) indicate that the operating potential of the units does not exceed 50 kV. Therefore, as a conservative measure, the dose conversion coefficients are selected based on 50 kV.
6. ANSI/HPS N43.17-2002 Dose Conversion Coefficient for frontal and rear exposures.

8.4 Dose to Scanned Individuals for ANSI/HPS N43.17-2009

Standard: The reference effective dose shall not exceed 25 μrem (0.25 mSv) per screening. The reference effective dose received by individuals from one facility shall not exceed 25 mrem (250 mSv) over a twelve month period. (ANSI/HPS N43.17-2009, 6.1.1.1)

Assessment Results:

- The average effective dose per screening (frontal and rear scan) of a subject is 1.46 μrem (0.0146 μSv).
- Individual effective dose is below 25 mrem if an individual is subject to fewer than 17,123 screenings in a twelve-month period which is equivalent to 46 screenings per day (365 days per year).

Based on the data collected for dose to individual ANSI/HPS N43.17-2002 measurements as described in Section 8.3, dose to individual for ANSI/HPS N43.17-2009 was determined. The average effective dose per screening (frontal and rear scan) of a subject is 1.46 μrem (0.0146 μSv), as provided in Table 8-4. These measurements are based on the exposure readings and HVL data provided in Table 8-1, Table 8-2, Table 8-3, and Figure 8-4. The results provided are for the maximum dose derived from a master frontal scan at 30 cm from the master beam exit

panel and slave rear scan at 30 cm from the slave beam exit panel. Since the distance between these two points in the scan area is approximately 18.4 inches, it is conceivable that a scanned individual could be exposed to a consecutive master and slave scan at these locations.

Dose to scanned individuals for the two standards reported in this document differ due to the methods of calculation required by each standard.

Table 8-4. Subject Effective Dose per Scan and per Screening

	Average Exposure per Scan[3] (μR/scan)[4]	HVL	Dose Conversion Coeffiecient[5]	Effective Dose per Scan (μrem/scan)
Master Unit Scan[1] at 30 cm from Master Beam Exit Panel	4.71	1.18 mm Al	0.1298	0.61
Slave Unit Scan[2] at 30 cm from Master Beam Exit Panel	4.74	1.63 mm Al	0.1793	0.85

	Average Exposure per Screening[3] (μR/screening)[4]			Effective Dose per Screening (μrem/screening)
Master + Slave Unit (Frontal + Rear Scan)	9.45			1.46

1. Master unit scan at location 30 cm from master beam exit panel for total scan time of approximately 3 seconds.
2. Slave unit scan at location 30 cm from beam exit panel for total scan time of approximately 3 seconds.
3. Background exposure subtracted and energy correction factor of 1.02 applied.
4. Results provided above are for the maximum dose derived from a master frontal scan and slave rear scan.
5. ANSI/HPS N43.17-2009 Dose Conversion Coefficient for master unit is 0.1298 (0.110 * 1.18) and slave unit is 0.1793 (0.110 * 1.63).

8.5 Negligible Individual Dose

Standard: Negligible Individual Dose (NID) is set at 1 mrem (0.01 mSv) per year. At radiation exposures below the NID, efforts to reduce the dose further are not warranted. When the number of subject examinations results in exposures above NID, reasonable efforts should be made to reduce the number of scans, taking into account the nature of the application. (ANSI/HPS N43.17-2002, 5.3 Dose minimization and negligible individual dose and ANSI/HPS N43.17-2009, B.4 Dose minimization and negligible individual dose)

Assessment Results:

- Based on 1.55 μrem/screening for frontal and rear scans (per ANSI/HPS N43.17-2002, reference Section 8.3 of this report), individual dose is below NID if the individual is subjected to less than 645 screenings in a year.
- Based on 1.46 μrem /screening (per ANSI/HPS N43.17-2009, reference Section 8.4 of this report), individual dose is below NID if the individual is subjected to less than 684 screenings in a year.

NID for the two standards reported in this document differ due to the methods of calculation required for dose to individuals by each standard.

8.6 Dose to General Public, Bystanders, and Workers

A survey of the areas surrounding the master and slave unit of the system was conducted to determine the dose to general public, bystanders, and workers. This section provides a description of how the area survey was conducted, area survey data collected, and an explanation of calculations performed to determine dose to general public, bystanders and workers.

8.6.1 Area Survey

To conduct the survey the areas surrounding the master and slave units were designated by regions (A to B, B to C, C to D, D to E, E to F, F to G, G to H, H to A, A to D, H to E), as shown in Figure 8-6. An X-ray scattering source, four 5-gallon water-filled containers holding approximately 150 pounds of water, were placed in stacked bins at the center position between the two units, as shown in Figure 8-7. The system was placed in a special configuration to conduct the area survey.

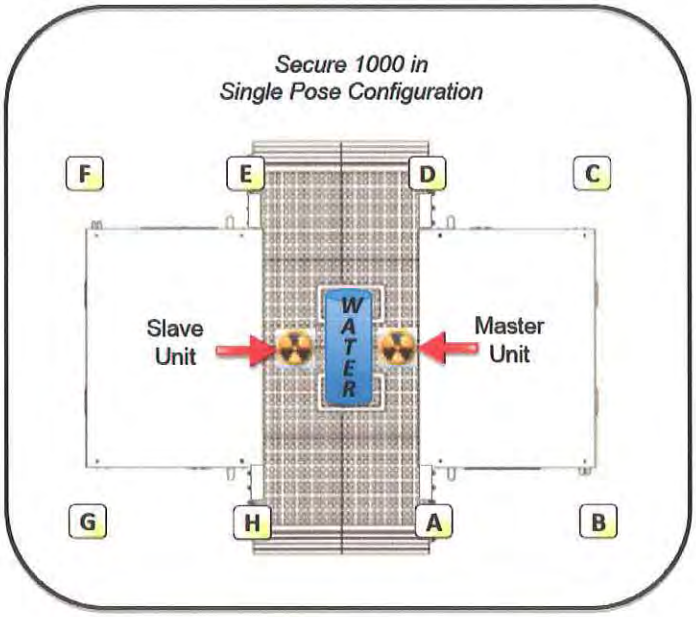
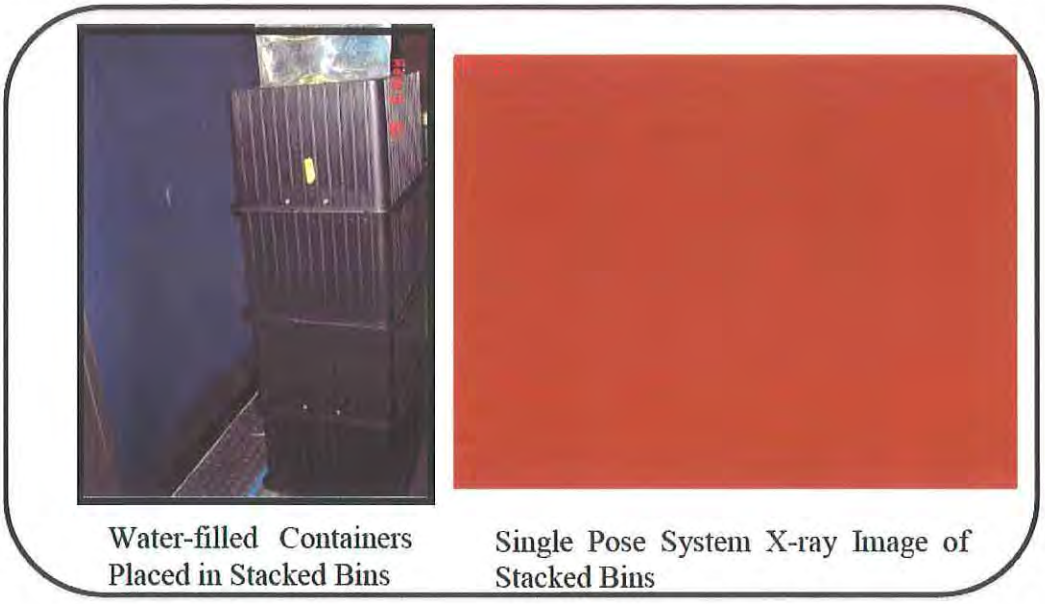


Figure 8-6. Regions for Area Survey



Water-filled Containers Placed in Stacked Bins

Single Pose System X-ray Image of Stacked Bins

5 USC 552(b)(4)

Figure 8-7. X-Ray Scattering Source

When used in the operational mode, the Single Pose system X-ray scan is less than 6 seconds in duration (less than 3 seconds for the master unit and less than 3 seconds for the slave unit). It was determined that since X-ray tube assembly [redacted] in less than 3 seconds, the X-ray tube would need to be stationary and the scan time longer in order to identify the area with the highest radiation reading and determine dose measurements. To facilitate JHU/APL area survey test methodology, Rapiscan engineers used the servicing mode to operate the master and slave units one at a time and manually command the system to scan. Rapiscan engineers conducted 10-second scans on a single unit (master or slave) while the second unit was not operated. Additionally, Rapiscan engineers were asked to place the X-ray generator on each unit at three different stationary positions (high, middle, and low as shown in Figure 8-8) in order for the area survey to be conducted. The system was configured for maximum operating parameters 50 kV, [redacted]

5 USC 552(b)(4)

Figure 8-8. X-ray Generator Position During Area Survey

Each region surrounding the master unit (A to B, B to C, C to D, H to A, D to E, H to E (above the slave unit)) was surveyed followed by each region surrounding the slave unit (E to F, F to G, G to H, H to A, D to E, A to D (above the master unit)). The following steps were conducted for each region surveyed:

1. The X-ray tube was placed in a stationary position at a height 59 inches from the ground.
2. During multiple 10-second scans, the region was surveyed using the Ludlum Measurements Inc. Model 3 Survey Meter. Scans were repeated until the area with highest radiation reading was identified.
3. At this location, the counts per minute (cpm) reading from the Ludlum was recorded. An additional reading using the plastic scintillator was recorded to get a dose measurement (rem).
4. Steps 1-3 were repeated with the X-ray tube placed in a stationary position at height of 39 inches from the ground.
5. Steps 1-3 were repeated with the X-ray tube placed in a stationary position at height of 19 inches from the ground.

Table 8-5 provides the highest radiation reading data for the areas surrounding the master unit. Table 8-6 provides the highest radiation reading data for the areas surrounding the slave unit. Using the data from these tables, the location with the highest radiation reading in each region was identified and at that location precise readings of the radiation exposure (R) were made using the 1800 cc ion chamber. Figure 8-9 shows the ion chamber positioned at location 3 and 12. The following steps were conducted for the location of highest radiation reading in each region:

1. The 1800 cc ion chamber was placed at the location with the highest radiation reading.
2. Five scans were conducted with the system operating under maximum operating parameters using operational 6-second scans (note that the system was used in the standard operational scan mode), where the master unit conducts a 3-second scan and is

immediately followed by the slave unit conducting a 3-second scan. Readings were recorded.

3. Five readings of background exposure were conducted for a 6-second time period.

Table 8-7 provides the exposure and background readings for the master unit and Table 8-8 provides the readings for the slave unit. Figure 8-10 provides the locations of the readings. As shown in Table 8-7 and 8-8, the dose above the units [redacted] 5 USC 552(b)(4)

that occurs at the beginning of each scan. When the Single Pose system executes a scan, the start position (for the first scan) of the X-ray generator [redacted] When the scan is initiated, the X-ray generator (and therefore x-ray beam) [redacted] Therefore, the primary beam points toward [redacted]

[redacted] During this phase [redacted] are not monitored because as they are out of tolerance. [redacted] At this time it is assumed that [redacted] and these parameters are monitored. Therefore, there is approximately 0.5 seconds at the beginning of each scan where vertical motion has not reached peak velocity and may result in slightly higher doses at the position where the scan starts.

Figure 8-9. Ion Chamber at Location 3 and 12 During Area Survey

Table 8-5. Master Unit Regions with Highest Radiation Reading

Master Unit					
Region	**X-ray Tube Height from Ground (Inches)**	**Radiation Instrument Height from Ground (Inches)**	**Radiation Instrument Distance from Left Side of Unit (Inches)**	**Ludlum Survey Meter with 44-3 (cpm)**	**Plastic Scintillator (µrem/hr)**
A to B	59	59	4.5	5,000	40
	39	42	17.5	10,000	Not Distinguishable[2]
	19	26.5	10	11,000	Not Distinguishable[2]
B to C	59	50.5	26	400,000	70
	39	36.5	26.5	250,000	40
	19	39	27	Over Range[1]	130
C to D	59	54.5	15	110,000	30
	39	37.5	15.5	100,000	18
	19	26	19.5	40,000	15
D to E	59	48.5	17	120,000	15
	39	41.5	At Wing	300,000	20
	19	13	9	50,000	15
H to A	59	71	17	3,000	11
	39	43	At Wing	500,000	30
	19	14	29 in. from Location H	50,000	10
H to E (On Top of Slave Unit)	59	108	24 in. from Left Side, 13 in. from Front of Unit	Over Range[1]	5
	39	108	24 in. from Left Side, 13 in. from Front of Unit	Not Distinguishable[2]	N/R[3]
	19	108	24 in. from Left Side, 13 in. from Front of Unit	Not Distinguishable[2]	N/R[3]
A to D (On Top of Master Unit)	59	108.5	24 in. from Left Side, 13 in. from Front of Unit	20,000	< 10
	39	108.5	24 in. from Left Side, 13 in. from Front of Unit	Not Distinguishable[2]	N/R[3]
	19	108.5	24 in. from Left Side, 13 in. from Front of Unit	N/R[3]	N/R[3]

Note 1: Ludlum Survey Meter range is limited to 600,000 cpm.

Note 2: Reading taken during X-ray scan was not distinguishable from background reading.

Note 3: No readings were taken (N/R). Maximum readings found to be at the 59 inch X-ray tube height. Due to the time constraints, precise readings at other heights were not taken.

Table 8-6. Slave Unit Regions with Highest Radiation Readings

Slave Unit					
Region	**X-ray Tube Height from Ground (Inches)**	**Radiation Instrument Height from Ground (Inches)**	**Radiation Instrument Distance from Left Side of Unit (Inches)**	**Ludlum Survey Meter with 44-3 (cpm)**	**Plastic Scintillator (µrem/hr)**
D to E	59	72	At Wing	40, 000	10
	39	47	At Wing	590,000	70
	19	22	11.5	41,000	Not Distinguishable[2]
E to F	59	58	5	40, 000	14
	39	30.5	10.5	52,000	20
	19	26	8.5	110,000	10
F to G	59	52	24	Over Range[1]	1,800
	39	39	21.5	Over Range[1]	6,000
	19	28.5	26	Over Range[1]	6,000
G to H	59	63	45.5	110,000	16
	39	42	18.5	110,000	22
	19	14.5	5.5	220,000	30
H to A	59	71	At Wing	42,000	18
	39	46	At Wing	520,000	60
	19	17	5	42,000	Not Distinguishable[2]
A to D (Top of Master Unit)	59	108.5	24 in. from Left Side, 12 in. from Front of Unit	Over Range[1]	6,000
	39	108.5	24 in. from Left Side, 12 in. from Front of Unit	Not Distinguishable[2]	N/R[3]
	19	N/R[3]	N/R[3]	N/R[3]	N/R[3]
H to E (Top of Slave Unit)	59	108	24 in. from Left Side, 12 in. from Front of Unit	Not Distinguishable[2]	N/R[3]
	39	N/R[3]	N/R[3]	N/R[3]	N/R[3]
	19	N/R[3]	N/R[3]	N/R[3]	N/R[3]

Note 1: Ludlum Survey Meter range is limited to 600,000 cpm.

Note 2: Reading taken during X-ray scan was not distinguishable from background reading.

Note 3: No readings were taken (N/R). Maximum readings found to be at the 59 inch X-ray tube height. Due to the time constraints, precise readings at other heights were not taken.

Table 8-7. Master Unit Exposure Readings

Master Unit										
Location Number	Region	Ion Chamber Height from Ground (Inches)	Ion Chamber Distance from Left Side of Unit (Inches)	Ion Chamber Distance from Unit Panel (Inches)	Scan Number	Exposure Reading Ion Chamber (μR/screening[1])	Background Reading Ion Chamber (μR[2])	Average Exposure with Background Subtracted (μR/screening)	Energy Correction Ion Chamber	Average Exposure with Background Subtracted and Energy Correction Applied (μR/screening)
1	A to B	59	4.5	11.8 (30 cm)	1	0.28	0.14			
					2	0.21	0.21			
					3	0.21	0.21			
					4	0.21	0.14			
					5	0.21	0.21	Exposure reading was not distinguishable from background exposure.		
					Average	0.22	0.18			
2	B to C	39	27	11.8 (30 cm)	1	0.14	0.14			
					2	0.14	0.21			
					3	0.14	0.14			
					4	0.14	0.14			
					5	0.14	0.14	Exposure reading was not distinguishable from background exposure.		
					Average	0.14	0.15			
3	C to D	54.5	15	11.8 (30 cm)	1	0.21	0.14			
					2	0.14	0.14			
					3	0.21	0.14			
					4	0.21	0.14			
					5	0.14	0.14	Exposure reading was not distinguishable from background exposure.		
					Average	0.18	0.14			
5	D to E	41.5	At Edge of Wing	N/A	1	0.77	0.14			
					2	0.77	0.21			
					3	0.77	0.14			
					4		0.21			
					5		0.21			
					Average	0.77	0.18	0.59	1.02	0.60
9	H to A	43	At Edge of Wing	N/A	1	0.98	0.14			
					2	0.98	0.21			
					3	1.05	0.14			
					4		0.21			
					5		0.21			
					Average	1.00	0.18	0.82	1.02	0.84
12	H to E (On top of Slave Unit at 99 Inch Height)	99	24	13 from Front of Unit	1	1.34	0.21			
					2	1.41	0.21			
					3	1.34	0.21			
					4	1.34	0.14			
					5	1.34	0.21			
					6	1.34	0.21			
					7	1.34				
					8	1.34				
					9	1.34				
					10	1.34				
					Average	1.35	0.20	1.15	1.02	1.17
12	H to E (On Top of Slave Unit at 105 Inch Height)	105	24	13 from Front of Unit	1	0.70	0.07			
					2	1.55	0.07			
					3	0.70	0.14			
					4	1.55	0.14			
					5	0.70	0.14			
					6	1.55				
					7	0.70				
					8	1.48				
					9	0.70				
					10	1.48				
					Average	1.11	0.11	1.00	1.02	1.02

1. Master unit and slave unit consecutive scans for total scan time of approximately 6 seconds.
2. Background reading conducted for 6-second time period.

Table 8-8. Slave Unit Exposure Readings

Slave Unit										
Location Number	Region	Ion Chamber Height from Ground (Inches)	Ion Chamber Distance from Left Side of Unit (Inches)	Ion Chamber Distance from Unit Panel (Inches)	Scan Number	Exposure Reading Ion Chamber (μR/screening[1])	Background Reading Ion Chamber (μR[2])	Average Exposure with Background Subtracted (μR/screening)	Energy Correction Ion Chamber	Average Exposure with Background Subtracted and Energy Correction Applied (μR/screening)
4	D to E	47	At Wing Edge	N/A	1	0.21	0.14			
					2	0.21	0.14			
					3	0.21	0.07			
					4	0.21	0.21			
					5	0.21	0.14			
					Average	0.21	0.14	0.07	1.02	0.07
6	E to F	30.5	10.5	11.8 (30 cm)	1	0.07	0.07			
					2	0.14	0.07			
					3	0.07	0.07			
					4	0.07	0.07			
					5	0.14	0.07	Exposure reading was not distinguishable from background exposure.		
					Average	0.10	0.07			
7	F to G	52	24	11.8 (30 cm)	1	0.21	0.07			
					2	0.07	0.07			
					3	0.07	0.07			
					4	0.07	0.07			
					5	0.07	0.07	Exposure reading was not distinguishable from background exposure.		
					Average	0.10	0.07			
8	G to H	14.5	5.5	11.8 (30 cm)	1	0.14	0.07			
					2	0.14	0.14			
					3	0.14	0.14			
					4	0.14	0.14			
					5	0.14	0.14	Exposure reading was not distinguishable from background exposure.		
					Average	0.14	0.13			
10	H to A	46	At Wing Edge	N/A	1	0.21	0.07			
					2	0.21	0.14			
					3	0.28	0.14			
					4	0.21	0.14			
					5	0.21	0.14			
					Average	0.22	0.13	0.10	1.02	0.10
11	A to D (On Top of Master Unit at 104.75 Inch Height)	104.75	24	11.5 from Front	1	0.14	0.14			
					2	1.41	0.14			
					3	0.14	0.14			
					4	1.48	0.14			
					5	0.07	0.14			
					6	1.48				
					7	0.14				
					8	1.48				
					9	0.14				
					10	1.48				
					Average	0.80	0.14	0.66	1.02	0.67
11	D to A (On Top of Master Unit at 99.5 Inch Height)	99.5	24	11.5 from Front	1	0.28	0.14			
					2	1.34	0.14			
					3	0.91	0.07			
					4	1.27	0.07			
					5	0.49	0.07			
					6	1.27				
					7	0.35				
					8	1.34				
					9	0.84				
					10	1.27				
					Average	0.94	0.10	0.84	1.02	0.85

1. Master unit and slave unit consecutive scans for total scan time of approximately 6 seconds.
2. Background reading conducted for 6-second time period.

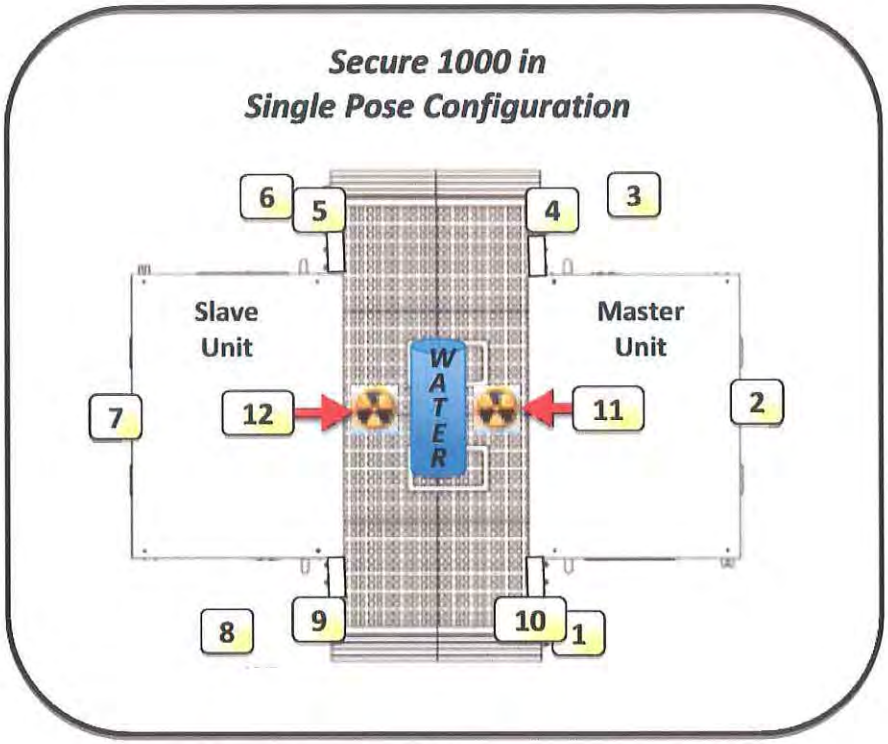


Figure 8-10. Locations of Highest Radiation Readings

8.6.2 Dose to General Public

Standard: NCRP 1993 recommends that members of the general public receive less than 1 mSv (0.1 rem) per year. These levels are subject to the radiation safety principle of ALARA. (ANSI/HPS N43.17-2002, 5.3 Dose minimization and Negligible Individual Dose and ANSI/HPS N43.17-2009, B.4 Dose minimization and Negligible Individual Dose)

Assessment Results:

- An area exists above each of the units, due to primary beam overshoot, where the 100 mrem per year general public dose limit could potentially be exceeded. This area extends up to a height of about 14 ft and 4.6 ft behind each of the units.
- A second area exists at the entry and exit locations of the scan area, where the 100 mrem per year general public dose limit could potentially be exceeded. This area extends approximately 1.7 ft from the side of the units at the entry and exit locations.
- The estimated annual dose and the associated exposed area are based on the maximum exposure readings taken at the time of the survey and from approximate geometric measurements of the X-ray beam path. A more precise measurement of the geometry would provide a better understanding of the area's boundaries, but was not possible due to the location of the system being evaluated.
- It is 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 100 mrem (0.1 rem) per year general public limit and to ensure that doses are kept ALARA.

- For the area above the units, a beam stop may be considered to ensure the general public dose is maintained.

Based on the data collected during the area survey as described in Section 8.6.1, dose to the general public was determined. An area above the units could potentially exceed the 100 mrem per year general public dose limit, as shown in Figure 8-11. This area extends to a height of approximately 14 feet from the ground and approximately 4.6 feet behind the units. Using the maximum dose of 1.6 μrem/screening (reference Table 8-7) at a location above the slave unit and using approximate geometric measurements of the X-ray beam path the distance at which the general public dose limit of 100 mrem/year was determined. These measurements assume 180 screenings per hour (30% duty cycle) and 100% occupancy for 2000 hours. It should be noted that this is a conservative assumption based on the maximum dose of 1.6 μrem/screening. As discussed in Section 8.6.1, the dose per screening above the slave unit was found to be dependent on the vertical motion of the X-ray generator. Doses are higher when the X-ray generator [redacted] as shown in Table 8-7 and 8-8. 5 USC 552(b)(4)

Using the maximum average dose measurements from the wing locations, an area that extends 1.7 feet from the sides of the units at the entry and exit locations could potentially exceed the 100 mrem per year general public dose limit, as shown in Figure 8-12. Using the maximum average dose measurement of 0.84 μrem/screening and approximate geometric measurements of the X-ray beam path, an approximate 100 mrem/year area was determined. These measurements assume 180 screenings per hour (30% duty cycle) and 100% occupancy for 2000 hours.

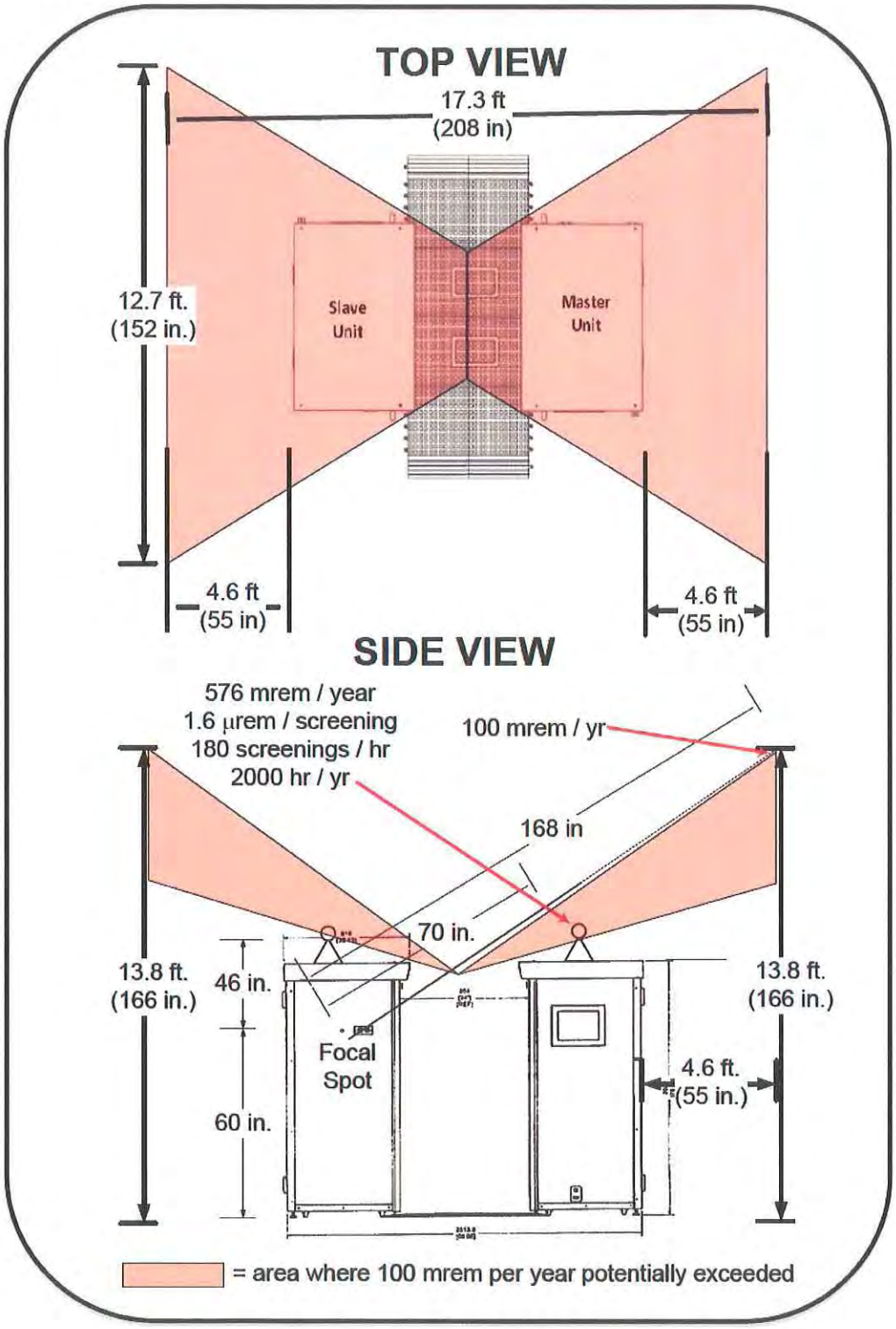


Figure 8-11. Dose to General Public Above Units

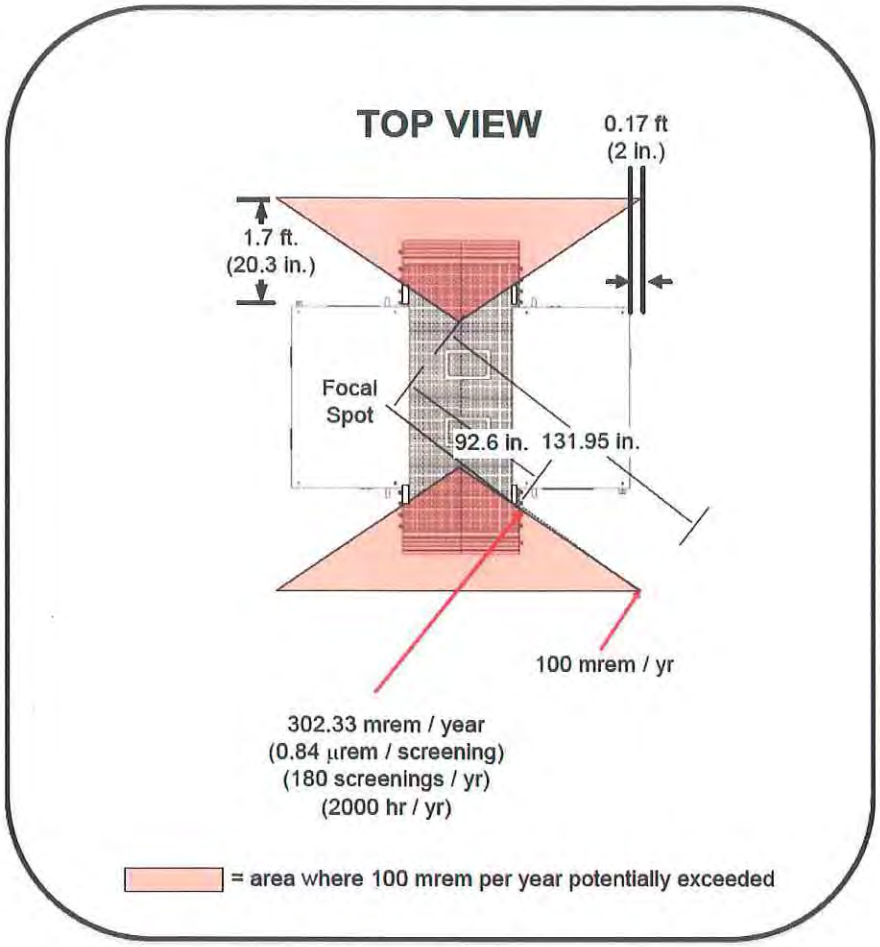


Figure 8-12. Dose to General Public at Entry and Exit Locations

8.6.3 Dose to Bystanders

Standard: Dose to bystanders outside of the inspection zone does not exceed 2 mrem in any one hour (ANSI/HPS-2002 N43.17, 5.4 and ANSI/HPS-2009 N43.17, 6.2) .

Assessment Results:

The dose to bystanders is within the requirements of ANSI/HPS N43.17-2002, 5.4 and ANSI/HPS-2009 N43.17, 6.2.

- Dose to bystanders varies from 0.043 to 0.704 mrem in any one hour at 100% duty and 100% occupancy.
- A more realistic dose to bystanders is from 0.003 to 0.053 mrem in any one hour with 30% duty factor and 25% occupancy factor applied.

Based on the data collected during the area survey as described in Section 8.6.1, dose to bystanders was determined. Table 8-9 provides the bystander dose measurements for the areas surrounding the master and slave unit and Figure 8-13 provides the locations where the 1800 cc ion chamber was placed for conducting exposure readings. The dose to bystanders is

indistinguishable from background radiation at the areas surrounding the right, back, and left side of the units (locations 1, 2, 3, 6, 7, 8). At the wings (locations 4, 5, 9, and 10) the dose to bystander varies from 0.043 mrem to 0.504 mrem in any one hour at 100% duty and 100% occupancy (from 0.003 mrem to 0.038 mrem in any one hour at 30% duty and 25% occupancy).

At locations directly above the units (locations 11 and 12), dose measurements were determined to assess the impact of primary beam overshoot on dose to bystanders that may occupy areas on floors or open spaces above the units. As discussed in Section 8.6.1, the dose per screening above the units was found to be dependent on the vertical motion of the X-ray generator. The dose to bystanders at locations directly above the units (locations 11 and 12) is 0.512 and 0.704 mrem in any one hour at 100% duty and 100% occupancy (0.038 and 0.053 mrem at 30% duty and 25% occupancy). Therefore the dose to bystanders outside of the inspection zone does not exceed 2 mrem in any one hour.

Performance differences were found between the master and slave X-ray units, the slave unit has a harder beam. This is reflected in the results of the dose to bystander measurements. Note that the dose at the wings that resulted from the master X-ray unit (locations 5 and 9) were higher than the dose that resulted from the slave X-ray unit. The dose measurements directly above the units from the master unit were also higher than the slave unit. Since the assessment was conducted with engineering units, this may not appear in production systems that are subject to the quality control process.

Table 8-9. Dose to Bystanders

Location	Average Exposure Reading (μR/screening[1]) Ion Chamber	Average Background Reading (μR[2]) Ion Chamber	Average Exposure with Background Subtracted and Energy Correction Applied (μR/screening[3])	Equivalent Dose for 100% Duty[4] and 100% Occupancy (mrem[5] in any 1 hour)	Duty Factor[6] (D)	Occupancy Factor[7] (T)	Equivalent Dose (mrem/screening x D x T) (mrem[5] in any 1 hour)
4	0.21	0.14	0.071	0.043	0.30	0.25	0.003
5	0.77	0.18	0.602	0.361	0.30	0.25	0.027
9	1.00	0.18	0.840	0.504	0.30	0.25	0.038
10	0.22	0.13	0.100	0.060	0.30	0.25	0.004
11	0.94	0.10	0.853	0.512	0.30	0.25	0.038
12	1.35	0.20	1.174	0.704	0.30	0.25	0.053
1, 2, 3, 6, 7, 8	Exposure reading was not distinguishable from background exposure.						

1. Master unit and slave unit consecutive scans for total scan time of approximately 6 seconds.
2. Background reading represents the average of 5 sequential 6-second background readings for each location.
3. Energy correction factor 1.02 applied.
4. 100% duty factor based on 600 screenings in one hour for 6-second scan time.
5. Assuming 1mR = 1 mrem.
6. 30% duty factor based on 180 screenings in one hour for 6-second scan time (vendor supplied information).
7. Occupancy factor for partial occupancy based on ANSI/HPS N43.3.-2008 Table A-1.

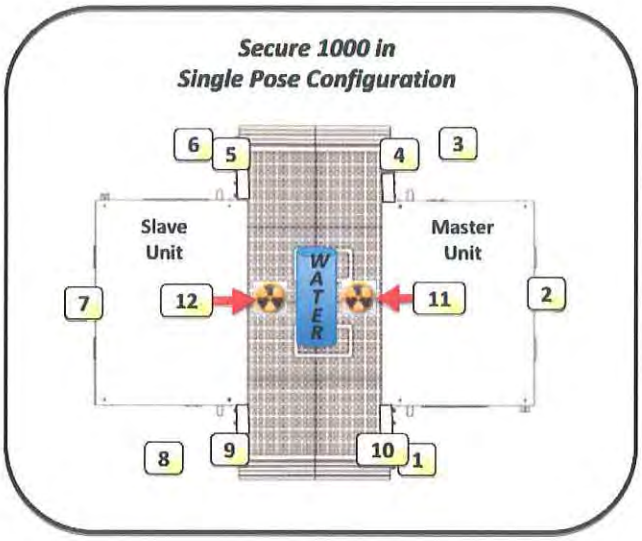


Figure 8-13. Locations for Dose to Bystander Measurements

8.6.4 Dose to Workers

Standard: Radiation dose to personnel at any work station does not exceed dose of 100 mrem/year (1 mSv) (ANSI/HPS N43.17-2002, 5.4 and ANSI/HPS N43.17-2009, 6.2)

Assessment Results:

The dose to personnel at any work station is below 100 mrem/year (or 50 μrem/hour) for 2000 hours/year when there are less than

- 476,304 screenings/year or
- 9,526 screenings/week or
- 1,905 screenings/day or
- 238 screenings/hour

Based on the data collected during the area survey as described in Section 8.6.1, dose to workers was determined. Table 8-10 provides the worker dose measurements for the areas surrounding the master and slave unit and Figure 8-14 provides the locations where the 1800 cc ion chamber was placed for conducting exposure readings.

Table 8-10. Dose to Workers

Location	Average Exposure with Background Subtracted and Energy Correction Applied (μR/screening)[1]	Number of Screenings per Hour for 30% Duty (screenings/hr)	Equivalent Dose for 30% Duty[2] (μrem/hour)	Occupancy Factor[3] (T)	Equivalent Dose for 30% Duty and 25% Occupancy (μrem/hr)	Number Hours Worked per Year (Based on 40 hours per week, 50 weeks per year) (hrs/year)	Maximum Dose per Year (Based on 2000 hours worked per year) (mrem/yr)[4]	Number of Screenings per Year to Reach 100 mrem (screenings/yr)	Number of Screenings per Week to Reach 100 mrem (Based on 50 Weeks per Year) (screenings/wk)	Number of Screenings per Day (Based on 5 Days per Week) (screenings/day)	Number of Screenings per Hour (Based on 8 Hours per Day) (screenings/hr)
4	0.071	180	12.85	0.25	3	2000	6	5,602,241	112,045	22,409	2,801
5	0.602	180	108.32	0.25	27	2000	54	664,673	13,293	2,659	332
9	0.840	180	151.16	0.25	38	2000	76	476,304	9,526	1,905	238
10	0.100	180	17.99	0.25	4	2000	9	4,001,601	80,032	16,006	2,001
1, 3, 6, 8	Exposure reading was not distinguishable from background exposure.										

1. Average exposure reading and background reading is provided in Table 8-9. Energy correction factor 1.02 applied.
2. Duty factor based on 180 screenings in one hour for 6 second scan time (vendor supplied information).
3. Occupancy factor for partial occupancy based on ANSI N43.3-2008 Table A-1.
4. Assuming 1 mR = 1 mrem.

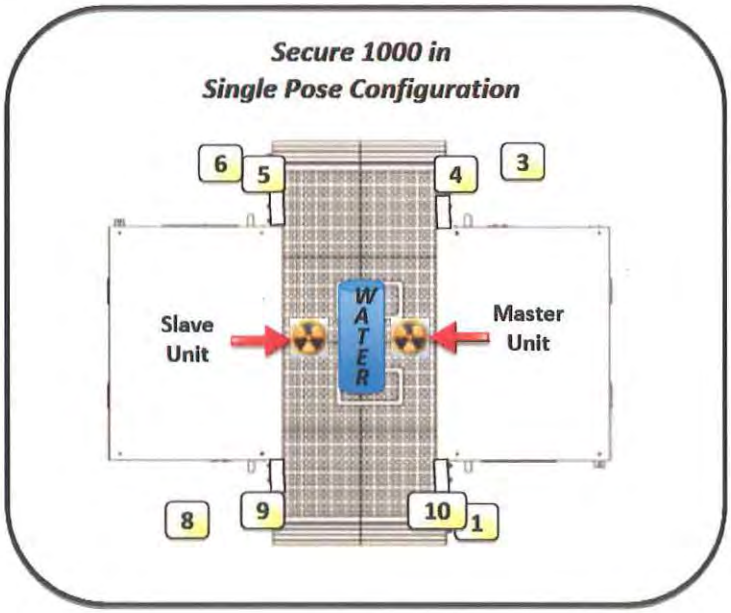


Figure 8-14. Locations for Dose to Workers Measurements

8.7 Leakage Dose Rate

Standard: Leakage dose rate at any point 30 cm from any external surface, excluding the beam exit surface, shall not exceed 0.25 mrem (2.5uSv) in any one hour (ANSI/HPS N43.17-2002, 5.5 Shielding and ANSI/HPS N43.17-2009, 6.3 Shielding)

Assessment Results:

- Leakage dose rate at 30 cm from any external surface of the master and slave unit are not distinguishable from background exposure using the 1800 cc ion chamber.
- The system meets the ANSI/HPS N43.17-2002, 5.5 and ANSI/HPS N43.17-2009, 6.3 Shielding requirements for sealed units.

Based on the data collected during the area survey as described in Section 8.6.1, leakage dose rate was determined. Figure 8-15 provides the locations where the 1800 cc ion chamber was placed for conducting exposure readings; these locations were 30 cm from the external surface of the unit. As indicated in Figure 8-15 and Section 8.6.1, these readings were taken with water placed between the master and slave units as an X-ray scattering source. Since it was found that the leakage dose measurements were not distinguishable from background exposure, it was not necessary to make additional measurements without a scattering source.

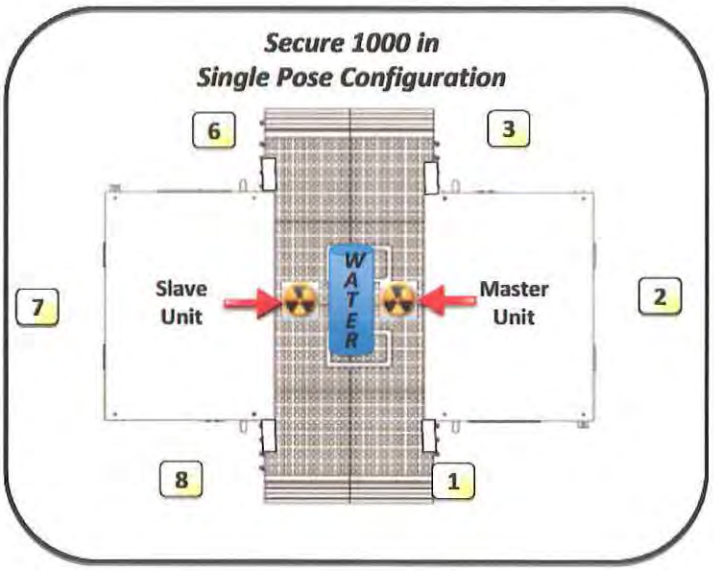


Figure 8-15. Locations for Leakage Dose Measurements

8.8 Physical Safety

Safety features related to operation and use of the Secure 1000 in Single Pose Configuration were reviewed and tested to ensure personal safety of operators, scanned individuals, and the general public and to verify compliance with ANSI/HPS N43.17-2002 and 2009. A series of tests, inspections and documentation reviews were conducted to assess the physical safety of the system. Note that ANSI/HPS N43.17-2009 7.2.1 (f), (h), (j), (m), and 7.2.2 (d), (e), and 7.6 (h) were not evaluated. The following sections provide assessment findings.

8.8.1 Indicators and Controls

Standard: ANSI/HPS N43.17-2002, 6.1 Indicators and controls. ANSI/HPS N43.17-2009, 7.2.1 Requirement for all systems (a), (b), (c), (d). ANSI/HPS N43.17-2009, 7.2.2 Requirements for general-use systems using x-ray sources (b).

Assessment Results: Rapiscan Secure 1000 in Single Pose Configuration meets the requirements of ANSI/HPS N43.17-2002, 6.1, ANSI/HPS N43.17-2009, 7.2.1 (a), (b), (c), (d), and ANSI/HPS N43.17-2009, 7.2. (b).

The system has two operational modes available to system operators, "managing" and "screening". Peak kilovoltage (kV), mA, and scan time [redacted] are preset by the vendor and are not alterable by the system operator at the inspection console with either operational mode. [redacted] 5 USC 552(b)(4)

Figure 8-16: "Servicing" Mode

In an operational setting there will be at least two operators, the inspection operator and the scanner operator. The inspection operator will be stationed at the inspection console at a location where the screening area (and the individual being screened) is not visible. At the inspection console, "managing" and "screening" modes are available, however, the system must be in the "screening" mode to conduct scans. [redacted] 5 USC 552(b)(4) The only mode available to the inspection operator is "scanning" mode. The responsibility of the inspection operator is to log in to the console at the beginning of the shift, view the X-ray images, and determine if the scanned individuals should be cleared or searched.

The scanner operator will be located near the exit of the scan area, where the scan button and status screen is mounted to the side of one of the units, as shown in Figure 8-18. Scans are executed by pressing the scan button shown in Figure 8-18. The operational scenario for scanning individuals is as follows:

- [redacted]

5 USC 552(b)(4)

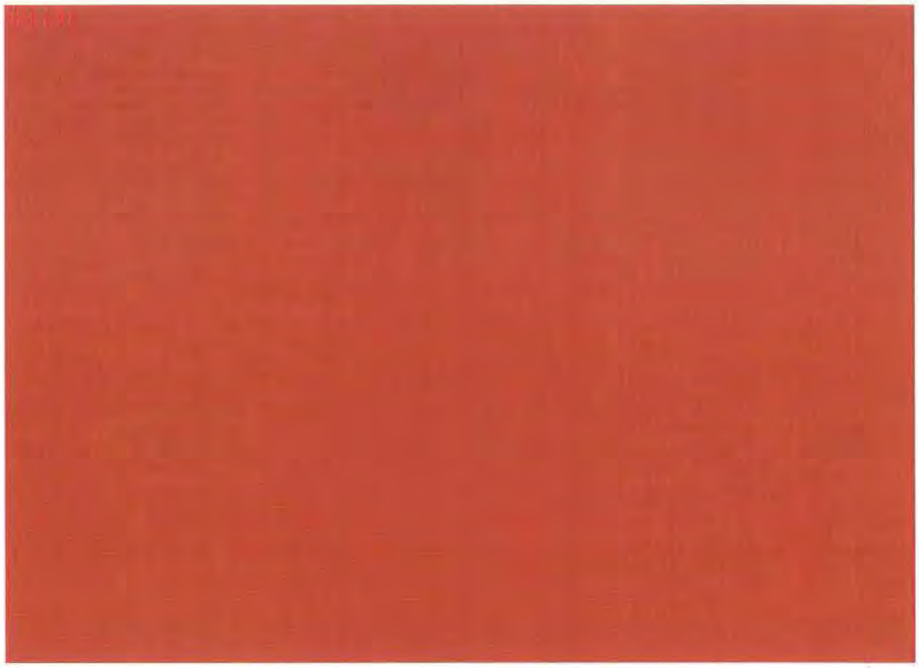


Figure 8-17: "Screening" Mode

Figure 8-18: Scan Button and Status Screen on Unit

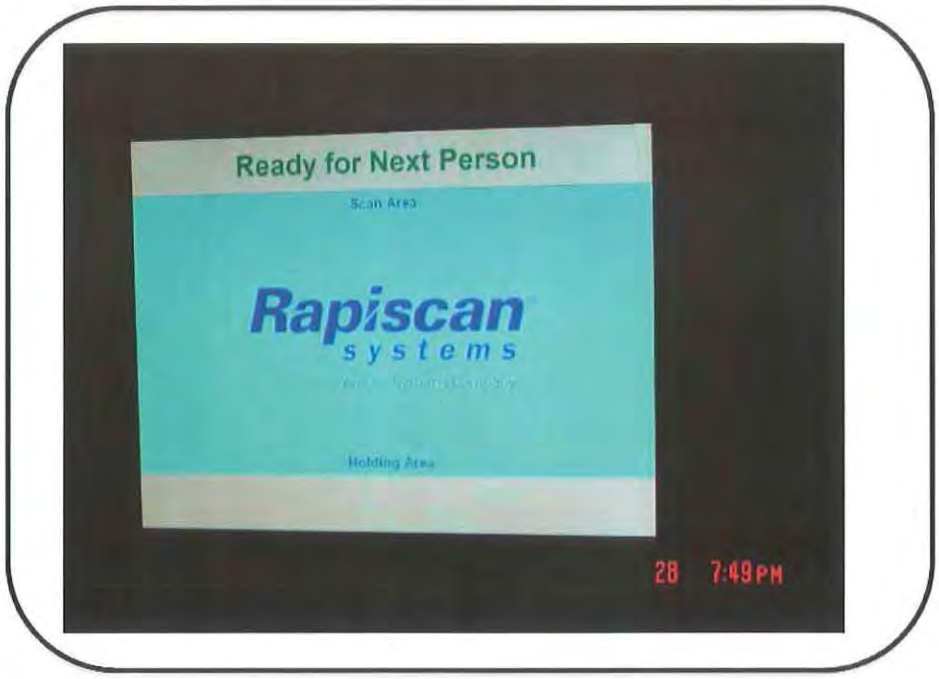


Figure 8-19: "Ready" for Scan Screen

Power to the system is controlled by a key switch, shown in Figure 8-20. The key switch has three positions, "off", "standby", and "on". When the key is placed on "standby" the system waits for commands from the operator console and will time out if commands are not received. A separate scan button, shown in Figure 8-18, is the only operational mode mechanism for executing a scan. Tests were conducted that verified that the following:

- To power the system, the key switch must be on "standby" or "on" position.
- X-rays are not emitted by turning on the key switch. This was verified with a radiation meter and operation of the key switch.
- The key is captured when it is in the ON position required for "screening" mode .

Figure 8-20: Key Switch

The "SCAN IN PROGRESS" light on the beam exit side of each unit is clearly visible and operates when a scan is in progress. Additionally, the screen on the side of the unit indicates that a scan is in progress. The light and screen are clearly visible from the location where the scan button can be operated, as shown in Figure 8-21.

Figure 8-21: Scan Indicator on Units

8.8.2 Access Panel Interlocks

Standard: ANSI/HPS N43.17-2002, 6.2.1 Access panel interlocks. ANSI/HPS N43.17-2009, 7.2.1 Requirement for all systems (i). ANSI/HPS N43.17-2009, 7.2.2 Requirements for general-use systems using x-ray sources (c).

Assessment Results: Rapiscan Secure 1000 in Single Pose Configuration meets the requirements of ANSI/HPS N43.17-2002, 6.2.1 Access panel interlocks, ANSI/HPS N43.17-2009, 7.2.1 Requirement for all systems (i), and ANSI/HPS N43.17-2009, 7.2.2 Requirements for general-use systems using x-ray sources (c).

Each Secure 1000 master and slave unit has access panels doors that require a key for access. Use of the key latches the top and bottom of the door. A mechanical sensor at the bottom of the door is depressed when the door is closed. If the door is opened, the sensor is released and the interlock prevents operation of the system. Tests were conducted that verified that the doors will not open without a key and that scans cannot be conducted when the doors are opened and the mechanical door sensor is released. The key lock and mechanical door sensor are shown in Figure 8-22.

Figure 8-22: Access Panel Door and Door Interlock

In the Secure 1000 Single Pose Configuration, the access panel interlocks of the two individual Secure 1000 units are not electrically connected. The interlocks are monitored logically in series from the master to slave unit by software on the operator's console. Both master and slave access panel interlocks must be enabled for a scan to initiate and complete. If the master access panel interlock is disabled, the slave unit is put in soft standby mode even if its access panel interlock is enabled. No scan is possible in this condition. If the master unit's access panel interlock is disabled by opening the door while a scan on the master unit is in progress, the scan terminates immediately and a scan with the slave unit is not initiated. If the slave unit access panel interlock is disabled when a scan on the master unit is in progress, the system will complete the master unit's scan and then terminate the scan.

8.8.3 Operational Interlocks

Standard: ANSI/HPS N43.17-2002, 6.2.2 Operational interlocks. ANSI/HPS N43.17-2009, 7.2.1 Requirement for all systems (l), (n).

Assessment Results: Rapiscan Secure 1000 in Single Pose Configuration meets the requirements of ANSI/HPS N43.17-2002, 6.2.2 Operational interlocks and ANSI/HPS N43.17-2009, 7.2.1 Requirement for all systems (l), (n).

The system has multiple operational interlocks that are monitored by the system and terminate X-ray production if thresholds are not met or discrepancies are detected. Based on technical discussions with Rapiscan engineers and the safety features description provided in Reference [9], the major system parameters monitored are as follows:

5 USC 552(b)(4)

- X-ray tube head kV and mA: This system operates at the maximum limits of the tube at [redacted] In addition, X-rays will terminate if there is over voltage or over current.

- Reference detector signal: A detector with a Photodiode is placed in the X-ray beam, the X-ray intensity is monitored for radiation levels out of range and detector signal is monitored for a level of 2.5 V with a low and high cutoff threshold of 1.92V and 2.92V.
- Velocity of vertical motion: An optical interrupter switch that travels with the X-ray tube generates electrical pulses to monitor vertical motion. [redacted] X-rays are terminated if vertical motion stops.
- Velocity of horizontal motion [redacted] of the scanned beam: An optical interrupt sensor located on the [redacted] assembly is used to monitor that the rotational velocity [redacted] is maintained [redacted] speed is monitored to determine if it is necessary to speed up or slow down [redacted] in order to achieve the correct frequency. X-rays are terminated if [redacted] speed is out of tolerance.
- X-ray tube head temperature: X-rays will terminate if the X-ray tube temperature is out of range.
- Main watch dog timer (monitor by software): Monitoring includes the reference detector, [redacted] vertical motion timer, microprocessor commands (X-rays terminated if commands are not received), and software malfunctions.
- Microcontroller (monitor by hardware): [redacted] Monitors include vertical motion, horizontal motion, and door sensor.

[redacted] The X-ray scan is terminated if at any time the monitoring circuits detect an abnormality. Note, Rapiscan provided a documented short description of the safety features (Reference [9]) and in discussion provided an updated description [redacted]

Testing was conducted that verified that the X-ray scan terminated if the door was opened (mechanical door sensor tripped) and that a normal control sequence is required to initiate a scan.

Standard: ANSI/HPS N43.17-2002, 6.2.2 Operational interlocks, subject exposure during a malfunction. In the event of a malfunction, the system shall terminate x-ray production rapidly enough to limit the subject exposure to a "dose times exposed area" of 250 μSv cm2 (25 mrem cm2). (For example: 25 μrem over a 1000 square centimeter area or 50 μrem over a 500 square

centimeter area, etc.). Additionally, no location on the subject's body shall receive a dose exceeding 25 mrem, regardless of the exposed area.

Assessment Results: Assuming maximum exposure time to a subject in the event of a malfunction is approximately 3 seconds, the maximum dose per area is 0.42 μrem/cm^2, which is significantly less than the 25 mrem cm^2 limit.

The assessment of subject exposure during a malfunction is based on a single point failure analysis, where the vertical motion of the X-ray tube stopped and was undetected by the system. Since the system limits the exposure time by monitoring the maximum number of scan lines, the maximum exposure time is limited to approximately 3 seconds. The total dose from a 3-second scan has been determined to be much less than the 10 μrem per scan limit. However, to be very conservative, a maximum dose of 10 μrem per scan will be used for the following analysis. [redacted] Assuming a subject width of 60 cm, an exposure of a 24 cm^2 area would result. Averaging the total dose of 10 μrem over a 24 cm^2 area results in a maximum dose per area of 0.42 μrem/cm^2. This is significantly less than the 25 mrem cm^2 limit specified by the ANSI N43.17-2002 standard. 5 USC 552(b)(4)

8.8.4 Emergency Stop Capability

Requirement: TSA requires that screening systems have an emergency stop capability. ANSI/HPS N43.17-2009, 7.2.1 Requirement for all systems (e).

Assessment Results: Rapiscan indicated that an emergency stop button is provided on the master and slave unit delivered to the TSL. The engineering system evaluated did not have the full emergency stop capability implemented, therefore it was not tested.

The Secure 1000 in Single Pose Configuration that JHU/APL evaluated was an engineering system, and the emergency stop button capability was not fully implemented on the units evaluated. The slave unit had an emergency stop button (shown in Figure 8-23), however the button connections were not wired to the system and the button was not operable. The master unit did not have an emergency stop button. Rapsican informed JHU/APL that in the system at TSL both the master and slave are equipped with emergency stop buttons.

Figure 8-23: Emergency Stop Button

8.8.5 Automatic Termination

Standard: ANSI/HPS N43.17-2002, 6.2.3 Automatic termination. ANSI/HPS N43.17-2009 7.2.1 Requirements for all systems (g).

Assessment Results: Rapiscan Secure 1000 in Single Pose Configuration meets the requirements of ANSI/HPS N43.17-2002, 6.2.3 Automatic termination and ANSI/HPS N43.17-2009 7.2.1 Requirements for all systems (g).

5 USC 552(b)(4)

JHU/APL measured the external emission of X-rays at the completion of the scanning cycle, and verified that no X-Rays were being emitted.

8.8.6 Ground Fault

Standard: ANSI/HPS N43.17-2002, 6.3 Ground fault. ANSI/HPS N43.17-2009 7.2.1 Requirements for all systems (g).

Assessment Results: Rapiscan informed JHU/APL that the system has an interlock that will terminate X-rays if there is a ground fault, as required by ANSI/HPS N43.17-2002, 6.3 and ANSI/HPS N43.17-2009 7.2.1 (g).

8.8.7 Labeling

Standard: ANSI/HPS N43.17-2002, 6.4 Labeling. ANSI/HPS N43.17-2009, 7.3 Labeling.

Assessment Results: Rapiscan Secure 1000 in Single Pose Configuration meets the requirements of ANSI/HPS N43.17-2002, 6.4 Labeling and ANSI/HPS N43.17-2009, 7.3 Labeling.

The master and slave unit each have a label that is permanently affixed to the system that includes the name and address of the manufacturer, manufacture date, model number, and serial number (see Figure 8-24). Since an engineering unit was evaluated, the serial number on the label was incorrect.

Figure 8-24: Secure 1000 in Single Pose Configuration Label

5 USC 552(b)(4)

ANSI/HPS-N43.17-2002, 6.4 and ANSI/HPS N43.17-2009, 7.3 require that the radiation source and shielding assembly have a clear and visible radiation warning label, and that this label is visible from any point where service access might be gained. JHU/APL verified the existence of this label (b)(4) however the label is affixed to the outside of the tube, and its visibility is dependent on the position of the tube. There is no label on the shielding assembly.

Figure 8-25: Radiation Warning Label

8.8.8 Modifications

Standard: ANSI/HPS N43.17-2002, 6.5 Modifications and ANSI/HPS N43.17-2009, 7.4 Modifications.

Assessment Results: Rapiscan informed JHU/APL that system changes are controlled by an Engineering Change Notice (Reference [10]), Request for Waiver, or Request for Deviation and that labels are updated to reflect any changes in compliance with ANSI/HPS N43.17-2002, 6.5 Modifications and ANSI/HPS N43.17-2009, 7.4 Modifications.

8.8.9 Information for the End User

Standard: ANSI/HPS N43.17-2002, 6.6 Information to be provided to the end user and ANSI/HPS N43.17-2009 7.5 Information to be provided to the end user.

Assessment Results: The draft Operator Manual (Reference [11]), draft Maintenance Manual (Reference [12]), and Specification Sheet (Reference [4]) provide the information required by ANSI/HPS N43.17-2002, 6.6 and ANSI/HPS N43.17-2009 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. Final documents should be reviewed when completed and it is recommended that document revisions include technique factors and other information required by ANSI/HPS N43.17-2009, 7.5 (a), (g), (h), (i), and (j).

Rapiscan provided a draft Operator Manual and Maintenance Manual that were being revised for the single pose configuration of the Secure 1000. JHU/APL reviewed the draft documents and verified that the documents include safety practices and warnings, licensing that may be required, operational procedures for safe operation, and preventive maintenance requirements for safe operation. The specifications sheet includes kV and mA, however, the manuals do not include the technique factors (peak kilovoltage, electrical current, scan time) for each mode and total aluminum equivalent filtration as required by ANSI/HPS N43.17-2002 and 2009. It is recommended that this information is included in the updated document and that the final documents be reviewed when they are complete. Additionally, it is recommended that information required by ANSI/HPS N43.17-2009, 7.5 (a), (g), (h), (i), and (j) are included in the revisions of the documents.

8.8.10 Records Maintained by Manufacturers

Standard: ANSI/HPS N43.17-2002, 6.7 Records to be maintained by manufacturers and ANSI/HPS N43.17-2009, 7.6 Records to be maintained by manufacturers.

Assessment Results: Rapiscan informed JHU/APL of processes and records that meet the requirements for ANSI/HPS N43.17-2002, 6.7 and ANSI/HPS N43.17-2009, 7.6 (a) through (g).

JHU/APL reviewed the requirements of ANSI/HPS N43.17-2002 6.7 with Rapiscan and Rapiscan indicated that there are processes and records in place the meet the requirements of 6.7. Quality control procedures are in place which include final factory acceptance testing prior to

delivery. Service notifications are used by the service department maintenance, service, and training.

8.8.11 Installation Procedures

Standard: ANSI/HPS N43.17-2002, 7.2 Installation and ANSI/HPS N43.17-2009, 8.1.2 Installation.

Assessment Results: Rapiscan's Site Acceptance Test (SAT) provides functional system tests and a radiation survey (Reference [13]) that must be completed and approved for system acceptance. Installation procedures were not provided. Since the system evaluated was installed by Rapiscan, requirements ANSI/HPS N43.17-2002, 7.2 Installation and ANSI/HPS N43.17-2009, 8.1.2 were not evaluated.

8.8.12 Radiation Surveys

Standard: ANSI/HPS N43.17-2002, 7.7 Radiation surveys and ANSI/HPS N43.17-2009, 8.1.7 Radiation surveys.

Assessment Results: An assessment of Rapiscan third party radiation survey reports is provided in Section 8.2 of this report. A review of the reports found that the surveys did not conduct a complete area survey with the two unit configuration to determine dose to bystanders, an X-ray scattering source was not used for the area survey, an assessment of radiation leakage with the two unit configuration was not conducted, the assessment was conducted with one unit active and the second unit inactive, and the reports did not include evaluation of other ANSI/HPS N43.17 requirements such as safety interlocks.

8.9 Radiation Safety Product Report

Standard: FDA C.F.R. 21 Subchapter J Part 1002 Radiation Safety Product Report, ANSI/HPS N43.17-2002 4. Federal, state, and local regulations, ANSI/HPS N43.17-2009 4. Federal, state, and local regulations.

Assessment Results: The existing Rapiscan FDA filing is for the Secure 1000 system, 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. The FDA responded to the 1992 filing stating *"...this product is not actively regulated under the device authorities of the Food Drug and Cosmetic Act (FFDCA). The Performance Standard for Diagnostic X-Ray Systems and Their Major Components does not apply to the Secure 1000."* (Reference [14], [15], [16]).

9. CONCLUSIONS AND RECOMMENDATIONS

A radiation safety engineering assessment of the Secure 1000 in Single Pose Configuration was conducted to measure, verify, and report the parameters of system performance against TSA requirements, ANSI/HPS N43.17-2002, ANSI/HPS N43.17- 2009, and C.F.R. Title 21 Chapter I Subchapter J Part 1002 Records and Reports. Concluding observations are as follows:

- The system provided for radiation safety evaluation was an engineering unit built by the Rapiscan engineering team using components from their inventory and configured to be at the same version level and functionally equivalent to the system evaluated at the TSL.
- Performance differences were noted between the master and slave engineering units that may not appear in production systems that are subject to Rapiscan's production and quality control processes. Where differences were noted the most conservative measurements were used.
- The dose to scanned individuals is within requirements of ANSI/HPS N43.17-2002, 5.1 limit of 10 μrem/scan of subject's front and of ANSI/HPS N43.17-2009, 5.1 limit of 25 μrem/screening.
- The dose to bystanders is within the 2 mrem in any one hour requirement (assuming 30% duty and 25% occupancy) for ANSI/HPS N43.17-2002 and 2009.
- The leakage dose rate is within the 0.25 mrem in any hour requirement for ANSI/HPS N43.17-2002 and 2009.
- The dose to workers is within the 100 mrem in any one hour requirement (assuming 30% duty and 25% occupancy for 2000 hours) for ANSI/HPS N43.17-2002 and 2009.
- Areas exist above the units and at the entry/exit locations where the 100 mrem per year general public dose limit could potentially be exceeded. It is 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 100 mrem (0.1 rem) per year limit and to ensure that doses are kept ALARA. For the area above the units, a beam stop may be considered to ensure the general public dose limit is maintained.
- The system provides necessary interlocks to prevent unauthorized system access and provides emergency stop buttons.
    - Since an engineering system was evaluated, only one unit had an emergency stop button and it was not wired, therefore functional performance could not be validated.
    - The vendor reported that the TSL system incorporated an emergency stop button on each unit (master and slave).
- Depending on the position of the generator, the radiation warning label on the X-ray tube may not be clearly visible. The label may need to be placed in a more visible location. The shielding assembly does not have a warning label as required by ANSI/HPS-N43.17-2002, 6.4 and ANSI/HPS N43.17-2009, 7.3.
- The Secure 1000 in Single Pose Configuration draft Operator Manual and draft Maintenance Manual provided were under revision, the final version of the documents should be reviewed.
- The draft Operator Manual, draft Maintenance Manual, and Specification Sheet provide the information required by ANSI/HPS N43.17-2002, 6.6 and ANSI/HPS N43.17-2009 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. 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, 7.5 (a), (g), (h), (i), and (j).

- Rapiscan's Site Acceptance Test (SAT) provides functional system tests and a radiation survey that must be completed and approved for system acceptance. Installation procedures were not provided. Since the system evaluated was installed by Rapiscan, requirements ANSI/HPS N43.17-2002, 7.2 and ANSI/HPS N43.17-2009, 8.1.2 were not evaluated.
- The existing Rapiscan FDA filing is for the Secure 1000 system, 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. The FDA responded to the 1992 filing stating *"...this product is not actively regulated under the device authorities of the Food Drug and Cosmetic Act (FFDCA). The Performance Standard for Diagnostic X-Ray Systems and Their Major Components does not apply to the Secure 1000."*

10. REFERENCES

[1] ANSI/HPS N43.17-2002, American National Standard Radiation Safety for Personnel Screening Systems Using X-rays, American National Standards Institute Inc., April 3, 2002

[2] ANSI/HPS N43.17- 2009 Final for Publication, American National Standard Radiation Safety for Personnel Screening Systems Using X-ray or Gamma Radiation, American National Standards Institute Inc., July 7, 2009

[3] U.S. Food and Drug Administration Title 21, Volume 8, Chapter I Food and Drug Administration Department of Health and Human Services, Subchapter J Radiological Health, Part 1002 Records and Reports

[4] Rapiscan Systems Secure 1000 DV Specifications Sheet

[5] Medical and Health Physics Consulting, Radiation Report on Rapiscan Systems Secure 1000, 21 March 2006

[6] Medical and Health Physics Consulting, Radiation Report on the Rapiscan Systems Secure 1000, 5 June 2008.

[7] Medical and Health Physics Consulting, Supplement to Report Dated 5 June 2008, 28 October 2008.

[8] National Institute of Standards and Technology Assessment of Radiation Safety and Compliance with ANSI N43.17-2002 Rapiscan Dual Secure 1000 Personnel Scanner, 9 July 2008.

[9] OSI Systems Pvt. Ltd., Safety Features Secure 1000, Prepared by D. Anant, 10 July 2005

[10] Rapiscan Systems Engineering Change Notice Form R-0028-11, 2 April 2008

[11] Rapiscan Systems Secure 1000 Whole Body Imager Operator Manual Draft, Rapiscan Document Number 9210668, Revision 3, 15 April 2009

[12] Rapiscan Systems Secure 1000 Personnel Scanner Maintenance Manual Draft, Rapiscan Document Number 9210669, Revision 2, 15 July 2009

[13] Rapiscan Systems Secure 1000 Radiation Emission Measurement Form R-0338-4

[14] Department of Health and Human Services Letter to IRT Corporation (Mr. Crosby and Dr. Smith), Ref: OCS 9110663-03, 17 August 1992

[15] Smith, Steve W., Nicolet Imaging Systems, Detection of Objects Concealed Under Persons' Clothing Using the SECURE System, 77071-A11, November 1991

[16] Rapiscan Secure Products Secure 1000 Concealed Object Detection System, Addendum November 1998

APPENDIX A. CONFIGURATION OF THE SECURE 1000 SYSTEM IN SINGLE POSE CONFIGURATION

The following document was provided to JHU/APL by Rapiscan, and is the configuration document for the Secure 1000 System in Single Pose Configuration.