DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

The Honorable Edward J. Markey
House of Representatives
Washington, D.C. 20515-2107

FEB 09 2011

Dear Mr. Markey:

Thank you for your letter of November 23, 2010, regarding general use, full-body x-ray screening systems currently being used for airport security. We appreciate your desire, as well as the public's, for a full understanding of the safety of this technology.

As background, the Food and Drug Administration (FDA or the Agency) has no authority to require federal premarket "approval" of non-medical electronic radiation-emitting products. However, all manufacturers of electronic products that emit or could emit ionizing radiation are required to submit radiation safety reports to FDA prior to entering a new model into commerce. These manufacturers are also required to maintain radiation safety test records; submit a report annually that summarizes their radiation safety test and quality control results and safety communications; and make their records available to FDA for inspection for good cause.

In addition, manufacturers of any electronic product that emits radiation, including millimeter wave and general-use x-ray security systems, are required to notify FDA immediately upon discovery of any accidental radiation occurrence[1] or radiation safety defect.[2] In the event of a radiation safety defect, the manufacturer must also notify purchasers of the defective product.[3] If a manufacturer is not granted an exemption from notification, then it must submit a corrective action plan to FDA for approval that will involve repair, repurchase, or replacement of the affected products without charge.[4] This corrective action is processed as a recall.

We have restated each of your questions below in bold, followed by our responses.

1. **In the October 12th letter, the FDA mentions that the assumed skin dose of x-rays that was used to grant approval for the use of these machines was an estimate based on theoretical modeling. Additionally, the FDA mentions that it has in place survey teams that are collecting radiation dose data with mounted dosimeters placed within the inspection zone of the x-ray scanner. Where in the "inspection zone" will these dosimeters be placed? When will the data collection be completed? Does the FDA plan on making this data publicly available? If yes, when? Please describe what the FDA hopes to accomplish by collecting this data.**

[1] Title 21 *Code of Federal Regulations* (CFR) § 1002.20 *Reporting of Accidental Radiation Occurrences*
[2] Title 21 CFR § 1003.10 *Discovery of defect or failure of compliance by manufacturer; Notice requirements*
[3] Title 21 CFR § 1003.21 *Notification by the manufacturer to affected persons*
[4] Title 21 CFR § 1004 *Repurchase, Repairs, or Replacement of Electronic Products*

Will the FDA use this data to validate its theoretical model using the actual measurements for passengers screened with these machines? If so, when will these efforts be completed and if not, why not?

The survey teams[5] referred to in the October 12 letter are from the U.S. Army Public Health Command (Provisional) (PHC) and were established by the Transportation Security Administration (TSA) via an agreement with the PHC to provide independent radiation safety surveys. Survey teams from the Army Institute of Public Health are performing the radiation surveys and dosimetry measurements mentioned in the October 12 letter.

FDA has not been provided with details of the radiation survey methodology (including location of the dosimeters) or target completion date of data collection. FDA intends to review the results of the PHC surveys and dosimetry studies when those results become available.

The results from the PHC survey will reveal if key measurements for each individual system are consistent with all other systems of the same model. Consistent performance would indicate that the manufacturer's quality control system is in a state of control. The long-term measurements with dosimeters attached to these systems may be useful in demonstrating that the measurement procedures and instruments specified in the standard are appropriate. These data are not required to further validate the theoretical modeling.

2. **Has the FDA, either through modeling or measurement, determined the dose that would be received by the eyes, which are covered by a thinner layer of skin than most other organs? If so, what was the outcome and if not, why not?**

Although the eye is not included in the calculation of effective dose, the dose the eye will receive will not exceed the dose to the testes, since the eye is surrounded by more tissue. Based on modeling of the delivered dose to the testes, a hypothetical system operating at the manufacturer-specified limit will deliver a dose to the eyes from one screening of less than 0.138 μSv (13.8 μrem). This dose is orders of magnitude less than the recommended annual equivalent dose limit for the lens of the eye for a member of the general public of 15,000 μSv (1,500,000 μrem), which is intended to prevent deterministic injuries.

3. **Were the population risk assumptions initially made regarding the use of these machines that they would be used for secondary screening only? Since, general-use full-body x-ray machines are now being used as a primary**

[5] The October 12 letter states, "Surveys of the recently deployed backscatter x-ray personnel security screening systems have been performed by an independent party to confirm compliance with the radiation dose-per-screening limits for general-use of the 2009 standard. All systems surveyed to date have been found to comply with the general-use dose-per-screening limit in that standard. In addition, our independent survey teams are gathering area radiation dose data by mounting dosimeters on (within the inspection zone) select systems."

screening tool. In FDA's view, do the individual and population risk assumptions that were made in the study of these machines and in their approval process change as a result of their actual use? If yes, how? If not, why not?

These products were understood to be intended as a primary screening method since the initial information was submitted to FDA in 1990. Therefore, the individual and population risk assumptions that were made do not change as a result of their actual use.

As noted above, FDA has no authority to require federal premarket approval of non-medical electronic radiation-emitting products.

4. **In the October 12th letter, the FDA states that the dose modeling revealed that a typical screening delivers approximately 69 μrem of radiation to the testes—higher than the 25 μrem per scan standard for general-use x-ray screening systems that was published by a FDA and the National Institute of Standards and Technology (NIST) working group in 2009. This per scan limit was defined on the basis that a general use x-ray screening system should deliver less than 1/1000 of the annual dose limit of 25 mrem, which is the national dose limit for radiation received by the general public from security screening systems. Has the FDA attempted to determine how the higher projected dose received by the testes may impact any localized risk for this particular organ? If yes, please describe what was found. If not, why not? Are there other organs that are also expected to receive a greater dose than the effective dose for the deployed product? Please provide all relevant information.**

Sixty-nine μrem is the dose to one organ. It is not a whole body effective dose. Therefore, it is not the standard by which an individual's risk from a whole body exposure to ionizing radiation should be calculated.

Risk assessments of the possible detrimental health effects associated with ionizing radiation exposure are based on the "effective dose" an individual receives. The quantity "effective dose" is the accepted standard in the scientific community. It was defined by the International Commission on Radiation Units and Measurements (ICRU) Report 57 *Conversion coefficients for use in radiological protection against external radiation* (1998) and provides a realistic indicator of radiation risk.[6]

Effective dose takes into account the dose to individual organs, the significance of that dose, and the relative biologic effectiveness of the type of radiation. The risk to an individual receiving solely a 69 μrem to the testes is less than the risk to that individual from a uniform whole body effective dose of 25 μrem.

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[6] See NCRP report no. 116 *Limitation of exposure to ionizing radiation* (1993) for information about risk estimates used for radiation protection.

Please note that the results from the 2006 dose modeling were used to calculate the maximum possible testicular dose from a hypothetical product that delivered the maximum dose per screening allowed under the standard[7] for a full-body general-use x-ray security system. A system that delivers the maximum dose per screening is not typical. A typical system is represented by the system tested by Johns Hopkins University Applied Physics Laboratory (JHU APL). That system was reported to deliver a reference effective dose per screening of less than 0.02 μSv (2 μrem). The dose delivered per screening to the testes by that system is less than 0.056 μSv (5.6 μrem).[8]

5. **There exists a subset of females, such as those who carry mutations in the breast cancer susceptibility gene BRCA, who have defects in DNA repair mechanisms and as a result are more sensitive to the damaging effects of ionizing radiation. Has the FDA investigated the effect that the low level x-ray radiation produced by this scanning equipment may have on this subset of the female population or on other individuals who might be more inclined to experience adverse health effects from lower doses of radiation? If yes, please describe what you found. If not, why not?**

The annual dose limit in the standard for security screening is based on the NCRP[9] recommendations for the annual effective dose limit for individual members of the general public.[10] NCRP's dose limitation recommendations for the general public were made with the understanding that the general public includes special populations that are more sensitive to radiation. An individual will receive an average of 3.3 μSv effective dose per hour of domestic air travel.[11] A single screening with the system tested by JHU APL would result in a dose that is less than 0.6% of the dose from 1 hour of domestic air travel. In other words, well over 99% of the ionizing radiation exposure that air travelers

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[7] ANSI/HPS N43.17-2009, *Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation*

[8] *Radiation Safety Engineering Assessment Report for the Rapiscan Secure 1000 in Single Pose Configuration*, Johns Hopkins University Applied Physics Laboratory, Assessment for TSA, October 2009 and revised August 2010

[9] NCRP was founded in 1964 by the U.S. Congress to "cooperate with the International Commission on Radiological Protection, the Federal Radiation Council, the International Commission on Radiation Units and Measurements, and other national and international organizations, governmental and private, concerned with radiation quantities, units and measurements and with radiation protection."

[10] NCRP Report 116, *Limitation of exposure to ionizing radiation* (1993); pages 45-47, 56: see also NCRP Statement 10, *Recent Applications of the NCRP Public Dose Limit Recommendation for Ionizing Radiation* (2004)

[11] NCRP Report 160, Ionizing Radiation Exposure of the Population of the United States; page 156 (2009). An international flight results in an average dose of 5.21 μSv per hour.

(including women with the BRCA gene, pregnant women, children, and developing fetuses) receive from a 1-hour flight comes from the air travel itself, not the security screening. As such, security screening does not appear to significantly increase the risk from ionizing radiation for these sub-populations, who are already undergoing air travel itself.

6. **Young children and developing fetuses are another subset of the population that have increased sensitivity to the damaging effects of radiation. Has the FDA determined the cumulative risk of multiple exposures to the radiation emitted by the security scanning equipment for children and pregnant women? If yes, please describe what you found. If not, why not?**

Please see the answer to question 5 above. In addition, the annual reference effective dose limit is 25 mrem and the dose limit per screening is $1/1000^{th}$ of the annual dose limit. For the deployed systems, the manufacturer's dose-per-screening limit specification is 0.05 μSv (5 μrem), which is less than $1/5000^{th}$ of the annual dose limit. Any individual would have to be screened more frequently than once every 2 hours every day of the year to approach the annual limit.

7. **Is the scanning motion on the full-body x-ray screening systems uniform for the entire body or are particular areas of the body scanned at slower rates? Please describe. Is it possible for the scanning motion to be adjusted by the operator of the machine a) during scans or b) in between scans?**

Yes, the scanning motion is uniform. The operator cannot adjust the scan speed or any other parameters that could alter the dose per screening. In addition, there are automated sensors that monitor the scanning speed. If the speed in either direction does not remain within specification, safety systems will automatically stop x-ray production.

8. **What enforcement strategy does the FDA have in place to ensure that all screening systems and protocols in use remain in compliance with the general-use dose-per screening limit of 25 μrem?**

FDA has no regulatory authority to routinely monitor the performance of non-medical screening systems after installation. For federal agencies, the responsibility of monitoring x-ray screening system performance and maintenance after installation lies with the user facility (for airport security screening, this responsibility lies with TSA). FDA has requested that TSA inform us of all electronic product radiation safety issues. For non-federal owners of electronic radiation-emitting products, the use of those products is regulated by state governments.

FDA does have regulatory authority over the manufacturers of electronic radiation-emitting products and can conduct inspections of manufacturer facilities for cause.

9. Does the responsibility of monitoring the safe use of this equipment lie solely with the FDA or is it shared with the TSA? Please describe the monitoring plan(s) that are in place.

Responsibility for monitoring the safe use of TSA equipment lies solely with TSA. However, we continue to be actively involved in providing technical advice to TSA, and FDA encourages TSA's continued use of a qualified third party, such as PHC, to periodically test systems to ensure that they remain within specification. FDA has requested that TSA inform us of all electronic product radiation safety issues.

10. What policies does the FDA have to ensure that any inappropriate dosage that occurs as a result from either human error or malfunctioning of the equipment is promptly reported to the FDA and the individual(s) who are likely to have received a higher dose, and that the machines are repaired?

As noted above, FDA has requested that TSA inform us of all electronic product radiation safety issues. In addition, as stated in the introductory paragraph of this response, manufacturers of any electronic product that emits radiation, including millimeter wave and general-use x-ray security systems, are required to notify FDA immediately upon discovery of any accidental radiation occurrence[12] or radiation safety defect.[13] In the event of a radiation safety defect, the manufacturer must also notify purchasers of the defective product.[14] If a manufacturer is not granted an exemption from notification, then it must submit a corrective action plan to FDA for approval that will involve repair, repurchase, or replacement of the affected products without charge.[15] This corrective action is processed as a recall.

11. It has been reported that the millimeter wave security systems uses non-ionizing radiation – a safer alternative to the ionizing radiation used in x-ray scanners— in smaller quantities than the backscatter x-ray screening equipment to create a black and white three dimensional image for screening purposes. In FDA's view would replacement of backscatter x-ray security systems with millimeter wave security systems pose less risk for travelers and airport employees being screened?

Based on currently available information, FDA believes that the scanning health risks of millimeter wave security system and backscatter x-ray screening equipment are both less than negligible.[16]

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[12] Title 21 *Code of Federal Regulations* (CFR) § 1002.20 *Reporting of Accidental Radiation Occurrences*
[13] Title 21 CFR § 1003.10 *Discovery of defect or failure of compliance by manufacturer; Notice requirements*
[14] Title 21 CFR § 1003.21 *Notification by the manufacturer to affected persons*
[15] Title 21 CFR § 1004 *Repurchase, Repairs, or Replacement of Electronic Products*
[16] The dose delivered per screening by a full-body general-use x-ray security system is much less than a negligible individual dose (NID). The NID is defined by NCRP (see NCRP Report 116, *Limitation of exposure to ionizing radiation* (1993); pages 51 – 52) as an annual effective dose of 10 μSv (1000 μrem) per source or practice. An individual would need to be screened at least 40 times per year with a hypothetical system that delivered the maximum dose per screening allowed for a general-use system set in the standard, or 200 screenings per year with the systems in use by TSA, for any individual to receive an NID.

Thank you again for contacting us regarding this matter. If we can be of further assistance, please let us know.

Sincerely,

Jeanne Ireland
Assistant Commissioner
for Legislation