RESPONSE TO THE LETTER FROM DEPARTMENT OF HEALTH AND HUMAN SERVICES OF OCTOBER 12, 2010

There is Still No Rigorous Hard Data For The Safety of X-Ray Airport Passenger Scanners

The problem remains that the safety of the X-ray airport scanners has not been independently verified.

Recently the NIST report on the 'Rapiscan Secure 1000', the most widely deployed person X-ray scanner, and the Johns Hopkins report have been made available. However the Johns Hopkins report, which is the more detailed and significant because it refers to the widely deployed Single Pose system, does not hold to critical principles of scientific reporting. The document is heavily redacted with red stamps over the words and figures. In every case the electric current used which correlates one to one with X-ray dose has been specifically redacted. Thus there is no way to repeat any of these measurements. While the report purports to present the results of objective testing, in fact the JHU APL personnel, who are unnamed anywhere in the document either as experimenters or as authors, were not provided with a machine by Rapiscan. Instead they were invited to the manufacturing site to observe a mock-up of components (spare parts) that were said to be similar to those that are parts of the Rapiscan system. The tests were performed by the manufacturer using the manufacturer's questionable test procedures. Although the doses from Compton Backscatter screening are potentially low, the dose rates are very high, comparable to dose rates in CT machines. These dose rates far exceed the limits specified for the ion chambers that were used in both the JHU measurements and the field measurements using the Fluke 451 reported by the TSA. There are also issues related to the incomplete coverage of the ion chamber by the flying spot of the backscatter machine. The data given in the Johns Hopkins report indicate that there must be something wrong. The very large exposures measured for scatter radiation in the JHL report, 36% of primary exposure above the cabinets outside the direct beam path and 19% of primary exposure in the entrance and exit regions, strongly suggest that the measurement of primary exposure is too low. Scatter exposure is usually at most a few % of the primary exposure, which is consistent with the fact that only a few % incident X-rays are Compton backscattered calling into question the validity of the exposure measurement as well as the validity of this test equipment for a (intense) spot scanner. The report was apparently summarized by the JHU APL; however, without signatories, there is no accountability for the document.

Thus, important information has not been provided to the public regarding the beam intensity under operational conditions at airports [X-ray photons per unit area per unit time (because it is scanning)] and/or the related quantity – fluence (being the total energy delivered per unit area, which is equal to the intensity multiplied by the time the spot remains on a given area), values that would be especially useful in calculating the dose. Also the X-ray tube current used in the tests or in the airport setting, that

correlates directly with X-ray intensity has always been redacted. This directly bears on the number of X-rays produced. As an example of our concern, the X-ray dose is proportional to the current through the X-ray tube. Not having access to the current used in the JHU test, or in the field application of the scanner means that the measurements at JHU are irrelevant to the dose at the airport. There is also no data on the pixel size and overscanning ratio, which also bear directly on the dose delivered to subjects.

The statement in the HHS letter that the fluence is not a relevant quantity ignores fundamental physics. The spatial resolution is related to the spot size, in practice the size of the collimator in the chopper wheel. The ability to discern features in the image is related to the number of photons per pixel. The fluence is the number of photons divided by the spot area and the dose is directly proportional to the fluence (see the detailed derivation in Rez et al., *Radiat. Prot. Dosimetry*, vol. 145, pp. 75-81, 2011). Measurements of exposure, and hence dose, must be consistent with the signal to noise and resolution in the image and ultimately X-ray tube current. The fluence is the quantity that connects these variables.

The whole issue of software was not addressed. Since this kind of instrumentation is critically controlled by software, a careful analysis of the source code is essential. How was the software qualified? How do we know if there is a 'region of interest' when intensity, for better resolution, is increased/changed? Can the intensity of the beam on different machines/airport scanners be changed, for example? Thus, how rigorously are the values of intensity or beam current maintained or dialed up or down to adapt to particularly suspicious subjects?

Finally, there is the issue of the recently disclosed patent (and granted, #7826589 titled **'**Security system for screening people'), filed two years ago. This patent covers operation of a two-sided system in which each side has a source and a detector, and includes the ability to record a 'shadow' image generated by transmission from one side, being received on the other side, implying significant X-ray transmission capability (in addition to the backscatter mode) as well as the ability to compare stored images, which was claimed previously but was not done. What does the new capability mean for the configuration and modalities for those X-ray airport scanners already installed? Are the intensities of the beam now changed? How can one be confident that the scanners are in a known configuration, not continually changed (changing) with different X-ray doses?

At the end of the day what is the best guess for the X-ray dose? Estimates from the signal to noise and resolution of published images suggest that the entrance skin dose is about 2.5 μSv and the effective dose is about 0.9 μSv (Rez et al., *Radiat. Prot. Dosimetry*, vol. 145, pp. 75-81, 2011). The dose may be even higher, since we do not know the quantum efficiency of the X-ray detectors (which could be as low as 10% efficient). This best guess dose is compared to the JHU report dose of 0.02 μSv. There will be no substitute for a direct, independently verified intensity (fluence) and dose.

In summary, the independent testing of the safety of these specific scanners has not been rigorous nor has it been held to the standards usually associated with new devices before approval for utilization in the public sector. Usually the exact technology, as installed, is sent to a university, national laboratory or other outside facility that has the expertise to test, for an extended period of time to enable an in-depth study--usually by several independent groups. Different test equipment, optimal for this configuration, can be used at a site that specializes in the potential problems of this technology. The hardware and software is tested in all aspects, finally arriving at a place where the true capabilities of this system are totally known, similar to testing of new aircraft, spacecraft and other technology that impacts on a national level.

Modern Molecular and Cell Biological Studies Probing Health Issues of Whole-Body X-Ray Scanners Are Not Undertaken

It is still unclear how much damage to cells occurs with low dose X-rays. One of the most important points in the "Red Flags" section of our letter of April 2010 was that potential X-ray damage, primarily to skin cells and adjacent tissues, would lead to a 'damage response' by the cells. Thus, damaged cells would show DNA damage of various kinds and/or an increase in concentration of many proteins that attempt to repair the damage. Being able to demonstrate that the X-irradiation does not induce the 'damage response' as compared to a control sample just exposed to background radiation would establish that the machines at least do not have a high (potentially damaging) X-ray intensity. Interestingly, the 8-page HHS letter response did not even comment on this crucial point.

The research community has the methodology to unambiguously determine in a very sensitive way whether there is damage to cells after X-irradiation from the airport scanners. For example, a recent study using tissue culture cells (Rothkamm, M. & Lobrich, M., *Proc. Nat. Acad. Sci. USA* vol. 100, pp. 5057-5062) has shown that with low dose X-rays (1 mSv (1 mGy), a dose coming within 100 to 1000 times that of the potential X-ray scanner dose), the cells have unrepaired DNA double-strand breaks (DSB) that are detectable for several days [1 DSB/50 cells at 1 mSv (1 mGy) ionizing radiation]. Because, even with low X-ray doses, the whole body is exposed to the X-ray scanning (this will include a vast number of skin and adjacent tissue cells) and therefore many cells could, summed up *in toto*, be damaged. [Keep in mind that the damaged cells might be relatively rare (or organ specific), possibly amplified by drug/pharmaceutical therapy, and there will be complications because of the different genetic backgrounds (See Brenner, D.J., *Radiology*, vol. 259, pp. 6-10, 2011).]. Where are the studies utilizing mutant mice (Wang et al., *Cancer Cell*, vol. 19, pp. 114-124, 2011) looking for enhanced mutations/cancer? This does not have to be an exhaustive search, but a small pilot study looking for mutations/cancer to confirm that the beam intensity is truly small would be sufficient. In summary, this kind of research has not been done with the X-ray scanners.

An additional point regarding biological damage from X-ray sources is that usually radiation biology deals with the integrated radiation dose. However, there is a

phenomenon known as *dose rate*, the dose per unit time--usually a high dose in a short period of time--which could significantly influence damage. Dose rate, however, is poorly studied. In the few documented studies (for example, see Witcofski et al., *J. Nucl. Med.* Vol. 15, pp. 241-245, 1972), it was shown that for the same overall dose, a 2-5 fold increase in damage can result from a high dose rate (for the short exposure) compared to a reduced dose rate (at a longer exposure time). The X-ray airport scanners can be characterized by a high dose rate (see Peter Rez calculation, a dose rate comparable to hospital CT X-ray machines), which adds additional unknowns for the potential damage by this radiation.

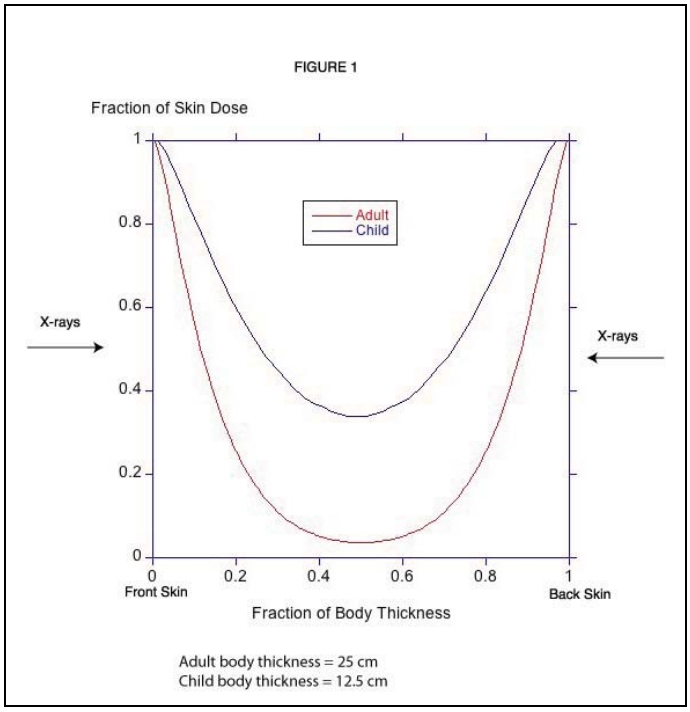
Human Biological Questions For X-ray Scanners Are Still Outstanding

We are still greatly concerned that not all tissues are equally exposed to the X-ray doses. We all now agree (see HHS letter) that the skin and adjacent (critical) tissues are especially exposed. Indeed, a recent paper (Kaufman, L. & Carlson, J.W., *J. Transp. Secur*. vol. 4, pp. 73-94, 2011, Fig. 5), as well as our Figure 1 below (taken from Peter Rez) show quantitatively how dramatic this is for this energy of X-rays. There are several potential consequences: First ocular (corneal) lens cells never regenerate in one's lifetime, thus are at risk for cataract and other problems. Second, there are now data that, contrary to past medical belief, X-rays will induce skin localized melanomas (Fink et al., *Radiat. Res*. Vol. 164, pp 701-710, 2005; (Eliason et al. *Arch. Dermatol*. Vol. 143, pp. 1409-1412, 2007). These are typically not counted under the criteria used of 'lethal cancers induced', under the criteria that skin cancers are rarely lethal cancers, simply because they can be seen, and if detected in time can be surgically removed. Third, the recent paper by Brenner (Brenner, D.J., *Radiology*, vol. 259, pp. 6-10, 2011) again emphasizes that a significant fraction of the population (~5%) is potentially at risk for increased sensitivity to X-rays. This fraction includes people undergoing chemotherapy, previous history of cancer, germ line mutations in DNA repair genes and people who are immunosuppressed. Fourth, there is likewise the issue of rescanning a subject after removing a belt, or an absorptive pad which would double, treble, or quadruple the dose received by the subject.

We call attention to the whole issue of 'effective dose'. Although effective dose is widely used in conjunction with the Linear No Threshold (LNT) model to predict carcinogenesis and mortality, it has serious shortcomings. The entrance skin exposure and the related entrance skin dose are quantities (see Fig. 1) that can be measured and are always higher than the "effective dose". The effective dose is an average where the dose in different organs is weighted according to factors published by the International Commission on Radiation Protection (ICRP). The conversion from entrance skin exposure to effective dose relies on modeling of X-ray interactions with mathematical representations of the human body (phantoms). The energy of X-rays for the widely deployed Rapiscan "Single Pose" system spans 0-50 keV with the average being 28keV. The dose follows an exponential decay and reaches half the value of the skin dose at a depth of 4 cm. Since organs near the center of the body are more strongly weighted the effective dose is a factor of 6 less than the entrance skin dose for an average male. However for small children, these internal organs receive a much higher

proportion of entrance skin dose, and the effective dose is much higher. The NIST report, using the crude Cristy and Eckerman phantoms, shows that the effective dose for children's organs is 1.5 times higher than the effective dose for adults. Examination of the figure below indicates that it might be higher. Moreover, radiation effects are more serious for children.

FIGURE 1



Critical Maintenance Issues For X-Ray Scanners Are Not Resolved

One of the most important issues is that a "Worst Case Failure" mode has not been evaluated. Because these machines are scanning mechanical/software integrated devices, with very intense pencil-like beams of X-rays, if they were to stop in the middle of a scan, there is the significant probability of a radiation burn. What are the consequences, if there were a software glitch or power, even momentary, problems? This important issue, on a machine working 24 hours a day, year in and year out, has not been studied independently and merits major efforts and extensive analysis, not just tested for failure once or twice, given the extreme consequences of a failure.

The casual nature for maintenance of these devices is alarming to us. These machines are built with components from clinical X-ray machines and are capable of delivering large X-ray doses. The actual doses are undefined by any objective tests disclosed to us or to the public. Large doses also pertain if there are errors or

maintenance problems. Hospitals usually check for problems on X-ray machines daily, but we understand that TSA will only check once a year, at best, in spite of the fact that these machines are being used 24 hours a day, 7 days a week.

The manufacturers are required to notify the FDA immediately upon discovery of an accidental radiation exposure. What is the trigger for discovery? What actions will the TSA personnel operating the system take in the event of a suspected malfunction? Will they notify the individual of exposure to a radiation level of 0.25 mSv, or a level considerably higher if the fail-safe mechanisms also malfunctioned? Who will be directly responsible for the medical care of passengers who are overexposed? How probable are these events? Have exhaustive tests of mean time between failures for these systems been done in realistic operational settings? How often will the machines be calibrated? The damage from an accidental overdose may not be quantifiable for many years after the exposure. It will be difficult to determine delayed medical consequences of overexposure.

In Summary, A Change is Needed

To summarize, the above points strongly indicate that independent test(s) have not been adequately performed for X-ray scanners leaving us in a situation where a major untested technology is being used on a large segment of our population, and where any damage may not be apparent immediately, or recognized to be caused by the extra radiation exposure – an unprecedented state of affairs.

We urge that independent testing and analysis of the entire technology be initiated immediately. Until then, given the potential health complications and the fact that a large segment of our population is being subjected to these machines as a primary screen, we strongly suggest that there be a moratorium on their primary use.

Finally, to end on a positive note, there are alternatives, that do not use ionizing radiation and that not only accomplish the same goal but also would be more effective. For example, scattering of high frequency electromagnetic waves, which are not ionizing radiation, is much more sensitive to differences between human tissue and high explosives. As another example, it is now possible to use a hand-held nanotechnology-based device that detects many/most high explosives with a sensitivity significantly surpassing a sniffer dog, the “Gold Standard” (see, for example, these directions: Engel et al., *Angew. Chem. Int. Ed. Engl*. vol. 49, p. 6830, 2010; Patolsky et al., *Nat. Protoc*. vol. 1, p. 1711, 2006). Rather than deploy systems that have the serious unknowns and potential shortcomings described above, why not use the great resources of our National Laboratories and our world-renowned entrepreneurial spirit to develop appropriate technologies that will reliably detect explosives and weapons that do not rely on invasive imaging?