From: s 47E(d)
To: s 47F @health.gov.au
Cc: s 47E(d) $ARPANSA Parliamentary Correspondence; s 47E(d)
Subject: TRIM: FW: URGENT: Request for input to Office of Transport Security on use of body scanners [SEC=UNCLASSIFIED]
Date: Wednesday, 11 May 2011 11:57:33 AM

Dear s 47F

We apologise for the delay in getting this information to you. We hope this is of assistance. Please free to contact us if you require anything further.

On the basis of the information ARPANSA has been provided with by the supplier of the L3 Provision millimetre wave scanner tested in Australia, exposure levels to people being scanned are exceptionally low, comparable to the exposure level from a mobile phone handset several meters away.

The higher frequencies used in the scanner tested in Australia means penetration into the human body will be lower than from most other exposures encountered in daily life.

Information provided by one supplier of medical implants (Section 22, Europe) indicates that the exposure of less than 1 volt/metre produced by the device would not affect their product.

There are European standards for the electromagnetic immunity of medical devices with immunity levels ranging from 3 V/m to 60 V/m depending on the application.

If devices manufactured or used in Australia meet similar standards, then the L3 Provision device should not cause any problem to wearers of implants.

The passive millimetre wave scanners do not rely on any emission of millimetre wave from the equipment and should present no problem apart from the normal potential for electronic equipment of any type to cause interference. We would expect this to be dealt with under normal standards intended to prevent interference.

Other models of scanners should be assessed for the EMC (electromagnetic compatibility) potential through examination of the manufacturers' specifications.

We would expect TGA to know, or specify, what EMC immunity specifications implants used in Australia meet.

Some background information we have been able to obtain from the supplier and other sources is summarised below.

Regards

s 47E(d)

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and

s 47E(d)
Senior Regulatory Officer,
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So far we have been able to determine the following with regard to electromagnetic interference - surgical implants (but not much within Australia) to inform our response to s 47F .

The **US Transport Security Administration** – Safety Sheet - states for both technologies (note: the US use the same mm-wave & backscatter scanners proposed for Australian use): "Advanced imaging technology screening is safe for all passengers, including children, pregnant women, and individuals with implants"

US Food and Drug Administration – Statement by Abiy Desta, Acting deputy Director, Division of Surgical, Orthopedic, and Restorative Devices – "Millimetre wave security systems that comply with the limits set by the Intitute of electrical and Electronics Engineers in the applicable non-ionizing radiation safety standard cause no known adverse health effects"

Of interest and for information only, the US FDA advises that "metal detectors, which can be walk-thru portals or hand-held, have the potential to affect the function of certain medical devices such as implanted cardiac pacemakers, implantable cardioverter/defibrillators, and spinal cord nerve stimulators"

Information from one manufacturer, Section 22 (dated 01/08/2007), is that the L3 Provision scanner will not affect the functioning of their implanted Section 22 pacemaker, defibrillator, or neurostimulator systems.

From the UK **Medicines and Healthcare products Regulatory Agency (MHRA)**, the following information (dated 29/11/2010) which I have highlighted:

Airport security body scanners and implanted electronic medical devices such as pacemakers, implantable cardioverter defibrillators (ICDs) and neurostimulators

During their travels air passengers will encounter electromagnetic radiation from a number of sources, including body scanners, metal detectors and screening wands, as well as from the sun due to flying at high altitude. Electromagnetic radiation presents minimal risks to those with implanted electronic devices. The recently introduced airport security body scanners send high frequency electromagnetic waves over the body's surface. These electromagnetic waves pass through clothing and are reflected by the skin and do not enter the body. The energy reflected back is used to create an image of the person's body and items within their clothing. They are intended to detect items on the body's surface, not within the body.

MHRA advice

The MHRA is not aware of any evidence of interference problems between airport security body scanners and implanted electronic medical devices. If you have an implanted pacemaker, ICD or neurostimulator you can use airport security body scanners. You should walk through metal detectors normally and not wait within the detection zone. As with mobile phones, you should maintain a distance of 6 inches (15 centimetres) between the screening wand and the implanted device. Patients are reminded to carry their registration card with their device details on to assist airport staff when passing through security checks. Although the flight itself does not present any increased risks of interference to the implant, be aware that you may find yourself in closer proximity to wireless technology on board an aircraft than you would on land. For further information relating to your own specific implanted device please contact your local cardiac centre, doctor or the manufacturer of your device.

Background information

There are two main types of body scanner in use at present: backscatter X-ray scanners, and terahertz or millimetre wave scanners.

Backscatter X-ray scanners

These systems use low energy X-rays that are reflected off the skin to form an image. The amount of radiation emitted during a body scan is typically 40 to 80 times less than the radiation experienced during the flight itself (depending on the length of the flight). This is approximately 100 times less than that from one day of natural background radiation [1], and around 1,000,000 times lower than that known to interfere with active implants [2,3].

Terahertz or millimetre wave scanners

These use radio waves, which can penetrate clothing. They can be either active or passive. Passive devices use the energy naturally emitted by the human body to form an image. Active devices produce radio waves that are reflected off the skin to form an image. The energy emitted by these systems is around 100,000 times less than a mobile phone transmission [4]. The frequency of the electromagnetic radiation used in terahertz or millimetre wave scanners and backscatter X-ray scanners does not pass through the skin and is not known to interfere with pacemaker, ICD or neurostimulator technology.

References

1 Health Protection Agency. Body scanning at airports. http://www.hpa.org.uk/Topics/Radiation/UnderstandingRadiation/UnderstandingRadiationTopics/BodyScanners/

2 Effects of CT Irradiation on Implantable Cardiac Rhythm Management Devices. Radiology: Volume 243: June 2007

3 Does High-Power Computed Tomography Scanning Equipment Affect the Operation of Pacemakers? Satoshi Yamaji, MD et al Circ J 2006; 70: 190-197

4 USA Homeland security. Privacy Impact Assessment for TSA Whole Body Imaging. http://www.dhs.gov/xlibrary/assets/privacy/privacy_pia_tsa_wbi.pdf

Discussion

There appears to be certainty overseas that both scanner technologies (backscatter x-ray – Rapiscan Secure 1000 & A & E Smart Check, and L3 provision millimetre wave) are safe for use on persons with surgical implants. This certainty is surely related to the fact that these technologies have been in established operational use in the US and the UK for some time now and that they have been considered by the US FDA and the UK MHRA.

Based on the above we could in all probability be confident that being scanned by a Rapiscan Secure 1000 or L3 Provision scanner should have no adverse affects on the operation of medical implants. However, we are reluctance to translate that certainty into the Australian context without a thorough dialogue on the matter with the TGA and ALL suppliers of both scanners and implants. Either we need more time to consult with the TGA so as to provide rigorous advice to Health. We note the matter of interference with medical implants is excluded from the scope of the ARPANSA RPS 3 Human Exposure Standard for RF fields).

With more information and assurances we would be able to say something like this:

The US Transport Security Administration, US Food and Drug Administration, and the UK Medicines and Healthcare products Regulatory Agency (MHRA) advise that the use of backscatter x-ray and millimetre wave scanners (of which the Rapiscan Secure 1000 and L3 Provision scanners are being considered for use at Australian international airports) pose no known adverse interference affects on medical implants.

However the advice of the above government bodies, having being formed through the operational use of these scanners under local conditions and through the governance of local medical and healthcare authorities, may not necessarily translate completely with regard to any possible adverse affects on the operation of medical implants within Australia. With that in mind, it is recommended that the Therapeutic Goods Administration should be consulted for advice on any requirements or concerns regarding interference with the operation of medical implants arising from the use of these scanners.

With regard to general radiation safety of the public resulting from airport passenger screening utilising backscatter x-ray or millimetre wave scanners, ARPANSA advises:

For backscatter x-ray scanners - the amount of radiation received during a scan is very low and is comparable to the amount of radiation received from cosmic radiation to two minutes flying at cruising altitude, or less than 40 minutes of normal background radiation. It would require 10 000 to 50 000 scans a year to reach the dose limit for a member of the public. While any exposure to ionising radiation could potentially create an increased risk to cancer, the radiation risk resulting from the use of backscatter x-ray scanners is very low, even for a child or a pregnant woman. The use of these types of scanner within Australia will be subject to regulatory control.

For millimetre wave scanners – these scanners use non-ionising electromagnetic radiofrequency radiation to generate an image based on the energy reflected from the body surface. These scanners emit radiofrequency radiation levels thousands of times lower than that of a single mobile phone call, and the levels of exposure are well within the limits of exposure set for the public. As such, the proposed use of this type of scanner will not be regulated by any Australian radiation regulator.

For more information, please see ARPANSA Fact Sheet – Airport Passenger Screening Technologies
http://www.arpansa.gov.au/RadiationProtection/Factsheets/is_AirportScreening.cfm

Thanks
s 47E(d)

From: s 47F @health.gov.au [mailto:s 47F @health.gov.au]
Sent: Thursday, 5 May 2011 2:08 PM

To: s 47E(d)
Cc: s 47F @health.gov.au; s 47F @health.gov.au
Subject: URGENT: Request for input to Office of Transport Security on use of body scanners [SEC=UNCLASSIFIED]

Dear s 47E(d)

I have been approached by s 47F the Executive Director of the Office of Transport Security (OTS), to provide the Department's view on their potential use of body scanners that use millimetre-wave and backscatter X-ray technology. Specifically, they are seeking any concerns our Department may have in relation to the scanners' potential effect on the operation of therapeutic devices.

The Department proper does not have expertise in the matters being raised by OTS. However, ARPANSA has expertise in millimetre-wave and X-ray technology and TGA has expertise in the design and operation of therapeutic devices such as pace makers. I am therefore writing to seek your assistance (and have also written separately to TGA in the same terms) in formally advising OTS of any issues that you can see associated with the operation of therapeutic devices when they are exposed to the proposed scanning technology. Further information about the proposed scanners has been provided by OTS - see below.

Previous correspondence with OTS has been about the regulatory process which I believe is now well understood by OTS and we are aware that they have been liaising with ARPANSA on these matters. This current activity is about using our scientific expertise to provide advice and I recognise this may fall substantially outside your normal regulatory roles. I am aware that there has been some interaction between OHP and your organisations on this matter already but I think there is a need to obtain more formal advice in order to assist OTS.

I would be grateful if your organisations could examine the information available and provide written advice that we can compile into a DoHA response to OTS. As OTS have a tight schedule to get advice to their Minister, I would ask that you provide your views to us by COB 9 May. The contact area in the Office of Health Protection is the Border Health Section. If you need any clarification or further information please ask the Director of Border Health Section (s 47F) for assistance.

Thank you in advance for your assistance with this issue

Regards

s 47F
First Assistant Secretary
Office of Health Protection
s 47F

Millimetre-wave (L3 ProVision)

The L3 ProVision is a millimetre-wave body scanner that has an operating frequency of between 24 – 30 GHz. A test report of the ProVision conducted in the United States calculated the power density (transmitter power), at a distance 2 cm from the radiating antenna(s), to be 4 x E-6 milliwatts per centimetre squared. Other tests have put this figure at 5.02 x E-6 milliwatts per centimetre squared. According to the *IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz*, the maximum permitted exposure (MPE) for the public for a frequency range of 2 – 100 GHz is 1 milliwatt per centimetre squared. Based on this information, the incident power density that a person could be exposed to within the ProVision is significantly below the MPE levels specified in the IEEE Standard.
The TSA state on their website that millimetre-wave technology emits thousands of times less energy than a mobile phone transmission. L3 claim that their machine emits 10,000 less units of power than other commercial radiofrequency devices, such as mobile phones.

Backscatter X-ray (Rapiscan Secure 1000)

The Rapiscan Secure 1000 is a backscatter X-ray body scanner. The United Kingdom Health Protection Agency (HPA) measured the radiation dose from one scan from an X-ray backscatter unit (single or double scan) as 0.02 microsievert (micro Sv) or less. According to the report, the typical radiation dose a passenger is exposed to during a commercial flight is approximately 5 micro Sv/hour, therefore the total radiation dose from an examination (which might involve 2 or 3 scans) is less than that received from two minutes flying at cruising altitude, or from one hour at ground level. HPA recommends a dose constraint of 300 micro Sv/year to a member of the public from practices involving the deliberate use of ionising radiation sources. Therefore a passenger would need to be examined 5000 times before exceeding this constraint value (based on three scans per examination). HPA concluded that the potential doses received from the use of a correctly installed and used x-ray backscatter body scanner are likely to be very low and even in the case of frequent fliers the doses are unlikely to exceed 20 micro Sv/year.
(http://www.dft.gov.uk/pgr/security/aviation/airport/securityscanners/securityscanner/)

The TSA state on their website that the dose of radiation received is less than that a person is exposed two during two minutes of flight at altitude.
