Scientific Committee on Emerging and Newly Identified Health Risks

SCENIHR

Health effects of security scanners for passenger screening (based on X-ray technology)

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ABSTRACT

Due to increased concern over terrorist attacks on aircraft, new technologies have been developed to improve the efficiency of security screening of passengers. Some of these technologies use ionising radiation (X-rays). As the hazards related to ionising radiation include the well-known carcinogenic risk, as well as other health effects, the SCENIHR was asked to assess the risks related to use of security scanners for passenger screening that use ionising radiation.

The X-ray based security screening technology used in passenger screening relies on two techniques: backscatter or transmission. In the backscatter technique, radiation is reflected from the subject and detected to form an image of the body showing any concealed objects worn on the body. The transmission technique detects X-rays emitted by the equipment that pass through the body of the subject. Any concealed object provides an image by attenuating the radiation. While the backscatter technique can only reveal objects at the surface of the body, the transmission technique also shows objects within the body if their contrast differs sufficiently from the surrounding body fluids or tissue.

The effective dose, which takes into consideration the type of radiation and the sensitivity of the body parts exposed, is the best parameter to assess the health risk from ionising radiation. The effective doses per scanned passenger are in the μSv range for the transmission technique and less than 1 μSv for the backscatter technique. The organ doses have generally the same order of magnitude. For persons scanned three times every working day, security scanning would result in an incremental effective dose of approximately 300 μSv (0.3 mSv) per year for the backscatter technique and close to 3 mSv per year for the transmission technique (assuming doses of 0.4 and 4 μSv per scan, respectively). The latter would exceed the dose limit for the general public and hence would not comply with the current radiation protection standards for the very extreme of the most frequently screened and therefore highest exposed group. The former remains within the range characterised as negligible by the US National Council on Radiation Protection and Measurements (NCRP).

Short-term (deterministic) health effects due to tissue damage cannot result from the doses delivered by security scanners. The long-term effects of ionising radiation include an increased cancer risk, which is assumed to be directly proportional to the dose received, without a safe threshold. However, direct evidence of an increased cancer risk in humans is only available down to dose levels of 20-100 mSv.

For lower doses, the risk estimation rests on linear extrapolation, a reasonable approximation based on both empirical observations and mechanistic inference. Other health effects of ionising radiation, such as hereditary effects, increased risks of cardiovascular and cerebrovascular disease, as well as opacities of the lens of the eye, are not considered pertinent for this opinion as there is no convincing evidence of their occurrence at such low doses. The potential magnitude of cancer risk from doses received from security scanners cannot be estimated, but is likely to remain so low that it cannot be distinguished from the effects of other exposures including both ionising radiation from other sources (including natural) and background risk due to other factors.

While the expected health detriment will probably be very close to zero for any single scanned person, the assessment of acceptability of the introduction of the security scanners using X-rays for passenger screening should also take into account the possible effect at the population level. Due to the substantial uncertainty regarding the potential occurrence of any health effects, risks for special groups within the population could not be evaluated meaningfully, although a higher risk related to exposure in childhood was noted.

Keywords: X-ray security scanners, X-ray transmission, X-ray backscatter, health effects, passenger screening

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EXECUTIVE SUMMARY

Security screening of passengers at airports has been an issue of heightened concern since the terrorist attacks of September 11, 2001. New technology has been developed to increase sensitivity and improve efficiency of passenger screening compared with metal detectors. Some of the novel techniques involve applications based on ionising radiation (X-rays). As the hazards related to ionising radiation include the well-known carcinogenic risk, as well as other health effects, assessment of the risks related to use of security scanners for passenger screening was requested from the SCENIHR.

The international standards of radiation protection are based on the general principles of justification, optimisation and dose limitation. Justification requires consideration of the benefits obtained from use of radiation relative to the potential risks, to preclude any unnecessary radiation exposure. The benefits and risks can include a variety of gains (for example, security scanners mainly improved flight safety) and adverse effects (health risks, economic costs, etc.), which are not directly commensurate and therefore the weighing of the trade-off is not straightforward. Whether a technology or its application for a certain purpose is deemed acceptable is ultimately not a scientific issue, but a political decision influenced by social factors. Dose limitation means setting standards for limiting radiation exposure to each individual, to avoid or minimise any health risks. Optimisation entails reducing radiation exposure within practical constraints, as low as reasonably achievable. This means that just complying with the dose limits is not sufficient. The dose limit for the general public is 1 mSv per year and for occupational exposure 20 mSv per year (the former is applicable to all exposed groups except those operating the scanners).

The currently available security screening technology utilised in passenger screening is based on two techniques: backscatter or transmission. In the backscatter technique, radiation is emitted from an X-ray tube and the radiation reflected from the subject is detected to form an image of the body and to show dense objects worn on the body. To achieve this, the incident X-ray energy is chosen such that both the incident and the backscattered radiation penetrate the clothing. The transmission technique uses detection of higher energy X-rays that are emitted by the equipment and pass through the body of the subject after being attenuated by the tissues and any concealed objects providing an image. The backscatter technique only reveals objects on the surface of the body, while the transmission technique also provides some contrast for objects within the body i.e. in the body cavities. Safety features are required for the equipment to avoid overexposure in case of malfunction or inappropriate operating procedures.

The amount of radiation received by a subject can be measured and expressed in terms of various dose quantities. The physical measure is the absorbed dose, which indicates the amount of energy absorbed in the tissue. The effective dose, which takes into consideration the type of radiation and the sensitivity of the exposed body parts, is the best parameter to assess the health risk from ionising radiation. The effective doses per scanned passenger are in the μSv range for the transmission technique and <1 μSv for the backscatter technique. The organ doses have generally the same order of magnitude. The maximal annual doses would be received by persons scanned three times every working day and for such persons security scanning would result in an incremental effective dose of approximately 300 μSv (0.3 mSv for backscatter technology, assuming a 0.4 μSV effective dose per scan), and if transmission technology is used, close to 3 mSv (given a dose of 4 μSv per scan). The latter would exceed the dose limit for the general public and hence would not comply with the current radiation protection standards (although only for the very extreme of the highest exposed group). The former remains within the range characterised as negligible by the US National Council on Radiation Protection and Measurements (NCRP).

The health effects of ionising radiation include short-term effects occurring as tissue damage. Such deterministic effects cannot result from the doses delivered by security scanners. The long-term effects of ionising radiation include an increased cancer risk,

which is assumed to be directly proportional to the dose received, without a safe threshold. However, direct evidence of an increased cancer risk in humans is only available down to dose levels of 20-100 mSv. Also, experimental studies have shown biological effects at similar doses levels. The risk estimation for lower doses rests on linear extrapolation, which appears to be a reasonable approximation based on both empirical observations and mechanistic inferences. Other health effects of ionising radiation may include hereditary effects, increased risks of cardiovascular and cerebrovascular disease, as well as opacities of the lens of the eye. There is however, no equally convincing evidence of their occurrence at low doses as for cancer risk and they are not considered pertinent for this opinion. The potential magnitude of cancer risk from doses received from security scanners cannot be estimated with any precision, but are likely to remain so low that they cannot be distinguished from the effects of other exposures including both ionising radiation from other sources and background risk due to other factors. The expected health detriment will probably be very close to zero for any scanned person, but at the population level the possible effect cannot be ignored in the assessment of acceptability of the introduction of the security scanners using X-rays for passenger screening. Due to the substantial uncertainty regarding the potential occurrence of any health effects, risks for special groups within the population could not be evaluated meaningfully, although a higher risk related to exposure in childhood was noted.

1. BACKGROUND

The possibility of introducing security scanners on the list of eligible screening methods and technologies for screening persons was first proposed to the Council and the European Parliament on 5 September 2008 on the basis of the positive vote of the Member States' aviation security experts[1].

On 23 October 2008, the European Parliament adopted a resolution on the impact of aviation security measures and security scanners on human rights, privacy, personal dignity and data protection, requesting a more in-depth assessment of the situation[2], opposing the Commission's proposal. The Commission agreed to review these matters further and withdrew security scanners from its original legislative proposal. The draft legislation became Commission Regulation (EC) No 272/2009[3] to apply as of 29 April 2010.

The Commission consulted with all parties concerned and issued a first analysis on the use of security scanners: the Communication to the European Parliament and the Council on the use of security scanners at EU airports[4] of 15 June 2010. Following this Communication an in-depth impact assessment was carried out by the Commission. It concluded that security scanners are an effective method for the screening of passengers and should be authorised for use at EU airports under certain operational conditions and detection performance standards. The report also identified the need to avoid any risks to human health and to ensure the protection of fundamental rights.

Consequently, the Commission proposed to add security scanners to the list of the method for the screening of passengers and linked their use to a number of conditions. On 10 and 11 November 2011 the Commission adopted this legislation. The relevant elements of the package are contained in Regulations 1141/2011 and 1147/2011. In particular, under the new legislation security scanners are not mandatory for Member States and/or airports and can only be used at EU airports in accordance with minimum conditions such as for example that: security scanners shall not store, retain, copy, print or retrieve images; any unauthorised access and use of the image is prohibited and shall be prevented; the human reviewer analysing the image shall be in a separate location and the image shall not be linked to the screened person and others. Passengers must be informed about conditions under which the security scanner control takes place. In addition, passengers are given the right to opt out from a control with scanners and be subject to an alternative method of screening.

In order to safeguard citizens' health and safety, at this stage, the Commission has allowed Member States and/or airports to deploy only security scanners which do not use ionising radiation.

The methods currently allowed for passenger screening are laid down at point 1 of part A of the Annex to Commission Regulation (EC) No 272/2009 and are:

(a) hand search;

(b) walk-through metal detection (WTMD) equipment;

(c) hand-held metal detection (HHMD) equipment;

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[1]Aviation Security Committee of 9/10 July 2008.

[2]The EP Resolution (2008)0521 asked the Commission to: carry out an impact assessment relating to fundamental rights; consult the European Data Protection Supervisor (EDPS), the Article 29 Working Party and the Fundamental Rights Agency (FRA); carry out a scientific and medical assessment of the possible health impact of such technologies; carry out an economic, commercial and cost-benefit impact assessment.

[3]Commission Regulation (EC) No 272/2009 of 2 April 2009 supplementing the common basic standards on civil aviation security laid down in the Annex to Regulation (EC) No 300/2008 of the European Parliament and of the Council (OJ L91, 3.4.2009, p. 7).

[4] COM (2010)311.

(d) explosive detection dogs;

(e) explosive trace detection (ETD).

(f) security scanners which do not use ionising radiation

Commission Regulation (EU) No 185/2010 of 4 March 2010 lays down detailed measures for the implementation of the common basic standards on aviation security. Point 4.1.1.2 of the Annex determines that passengers can be screened by a hand search or by a walk-through metal detector. Additional requirements on combining different methods in order to achieve effective detection are included in EU security restricted legislation.

In the EU, some countries tested security scanners and have now introduced security scanners under the new rules. In the current international context, security scanners are being deployed at airports worldwide, especially in the USA which deploys currently several hundred security scanners. Russia has been using security scanners at airports since 2008 and will continue to deploy them more widely in the future. Other countries are either planning (e.g. Canada, Australia) or examining the possibility of introducing security scanners (e.g. Japan).

Four main security scanner technologies for passenger screening are currently on the market but this does not preclude other technologies from appearing:

Body scanning security technology	**Type of energy used and level of exposure**
Passive millimetre-wave	No radiation emitted
Active millimetre-wave	Non-ionising radiation (24-30 GHz range), 60 to 640 $\mu W/m^2$
X-ray backscatter	Ionising X-ray radiation between 0.02 and 0.1 µSv per screening
X-ray transmission imaging	Ionising X-ray radiation between 0.1-5 µSv per screening

While X-ray based security scanners are currently used in the USA and as a trial in one UK airport, several Member States (e.g. Italy, France, Germany and Austria) prohibit the use of ionising radiation for non-medical purposes.

The protection of workers and the general public from ionising radiation is regulated under Directive 96/29/EURATOM. Article 6 of this Directive specifies the basic principles of radiation protection, among them that "*Member States shall ensure that all new classes or types of practice resulting in exposure to ionising radiation are justified in advance of being first adopted or first approved by their economic, social or other benefits in relation to the health detriment they may cause*." According to the Directive, the use of X-ray security scanners are notified to the National Competent Authorities (Art. 3) and an authorization shall be required by the Member States (Art. 4). The Directive also sets cumulative dose limits for workers (Art.9) and for members of the public (Art. 13).

As indicated in the recently adopted legislation on security scanners, the Commission would like to receive information on the impact on human health of the technologies available on the market and in particular on the X-ray based security scanner technologies.

2. TERMS OF REFERENCE

The SCENIHR is asked:

1. To assess the potential health effects related to the use of all types of security scanners used for passenger screening which emit ionising radiation.

2. If any effects are identified under 1, to quantify the risks and, if feasible, to estimate the additional number of cases of diseases that are expected to occur in Europe due to the use of this technology at EU airports, differentiating between the general public and exposed workers as indicated below.

In its assessment, the SCENIHR is asked to consider in particular the risk for populations that are regularly exposed to such technologies (e.g. frequent flyers (to be defined), air crew, security workers operating the scanners and other airport staff) and potentially vulnerable groups (e.g. pregnant women, children).

The SCENIHR should compare the relative risk of such security scanners using X-ray based technologies to other security scanner technologies on the market.

As health protection against ionising radiation falls under the provisions of the Euratom Treaty, the SCENIHR is asked to consult in its assessment the Group of Scientific Experts[5] referred to in Article 31 of the Euratom Treaty (Art. 31 GoE), advising the Commission on radiation protection matters.

[5] http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm

3. SCIENTIFIC RATIONALE

3.1. Introduction and scope

To assess the potential harm, considering the link between radiation exposure and health risks, we need to estimate the amount of exposure of the various exposed groups due to the use of security scanners for passenger screening. As specified in the Terms of Reference (section 2), this opinion considers only the use of security scanners using X-ray technology at EU airports and deals only with radiation detriment. Justification of practices using ionising radiation as required by radiation protection legislation is beyond the remit of this opinion.

Ionising radiation is ubiquitous and everyone is continuously exposed to it. All Europeans received on average 1 mSv annually from background radiation from naturally occurring radionuclides in the ground and within the body. Another component of the natural radiation is cosmic radiation from space. In addition, we are exposed to indoor radon through inhalation to a widely varying extent (range 0.1-10 mSv). The predominant man-made sources of radiation are medical diagnostic and therapeutic applications with a wide range of doses resulting in a contribution of between approximately 20 and 50% of the collective dose to the population in the EU (The collective dose is computed from the product of the irradiated population and the average effective dose per person. The average effective dose per person due to diagnostic medical exposures has been estimated as 0.3-0.4 mSv in the UK and 1.8-2.5 mSv in Germany, while the average effective dose per person due to natural sources varies within Europe (as described above) with a median of about 2 mSv. The population average doses from therapeutic applications have not been determined because they only affect a small number of people, even if these people receive very high doses (Berrington de Gonzales et al. 2011, Maddams et al. 2011).

At exposure levels above hundreds of mSv, adverse health effects of ionising radiation have been well established. The current model for estimating risk of low dose ionising radiation (commonly defined as approximately 100 mSv) is based on linear extrapolation from experimental and epidemiological data obtained at higher doses. The assumptions concerning the shape of the dose-response curve are crucial for the assessment. A monotonic linear pattern (linear, no-threshold model) is commonly used, which is assumed to represent a prudent choice, because at very low doses and dose rates the effects become indistinguishable from the background. X radiation is a form of sparsely ionising radiation called low Linear Energy Transfer (LET) radiation. Present estimates of the long-term health effects of radiation exposure, such as cancer risk, are described in the International Commission for Radiation Protection (ICRP) publication 103 and are based largely on the average exposure to a population. Based on the recommendations of the ICRP (ICRP, 1998), radiation cancer risks relative to baseline are judged to be small at low doses up to a few mSv. Cancer risks at effective doses of the order of 1 μSv, such as those encountered in passenger security-scanners using X-rays, are unknown. It is unlikely that epidemiological studies or experimental studies with the present methodologies could, at such low doses, have a sample size large enough to provide sufficient statistical precision and power to distinguish the increment for determining risk estimates. At doses below 50 mSv, epidemiological studies have so far been unable to provide information on the shape of the dose-response curve for cancer risk although some guidance can be obtained from experimental studies at doses above 1 mGy. However, for risk assessment purposes, the ICRP assumes a linear dose-response relationship, with no lower threshold below which radiation would have no detrimental effect.

3.2. System and Legislative Framework for Radiation Protection

3.2.1. ICRP System of Radiation Protection

The system of radiation protection that is used across Europe and worldwide is based on the recommendations of the International Commission for Radiation Protection (ICRP) and of the International Commission on Radiation Units and Measurements (ICRU). The conceptual framework adopted by the ICRP in its publication ICRP 60 (ICRP 1991) is one of a System of Radiological Protection and builds on the System of Dose Limitation central to earlier ICRP documents such as ICRP 26 (ICRP 1977). ICRP 60 (ICRP, 1991) was substantially revised and updated in 2007 with the publication of ICRP 103 (ICRP 2007).

The ICRP system of radiation protection is based on three fundamental principles: justification, optimisation and dose limitation.

The principle of justification requires that any decision that alters the radiation exposure situation should do more good than harm; in other words, the introduction of a radiation source should result in sufficient individual or societal benefit to offset the detriment it causes.

The principle of optimisation requires that the likelihood of incurring exposures, the number of people exposed and the magnitude of their individual exposure should all be kept as low as reasonably achievable, taking into account economic and societal factors. In addition, as part of the optimisation procedure, the ICRP recommends that there should be restriction on the doses to individuals from a particular source and this leads to the concept of dose constraints.

The third principle of the ICRP's system of protection is that of dose limitation. This principle requires that the dose to individuals from planned exposure situations, other than medical exposure of patients, should not exceed the appropriate limits recommended by the Commission.

As part of the system of protection, ICRP publication 103 defines three categories of exposure situations (ICRP 2007), namely: *planned exposure situations* which involve the deliberate introduction and operation of sources; *emergency exposure situations*, which require urgent action in order to avoid or reduce undesirable consequences; and *existing exposure situations*, which include prolonged exposure situations after emergencies. By adopting this approach, in principle, the ICRP system of protection should be able to be applied to any situation of radiation exposure, including that associated with security screening. Within the ICRP system, security screening would be considered to be a planned exposure.

The ICRP recognises three categories of exposed individuals: workers, patients and members of the public. These categories of exposure are known as occupational, public and medical exposure. Occupational exposure is generally interpreted as radiation exposure of individuals as a result of their work. However, as radiation is ubiquitous only those exposures that can reasonably be regarded as the responsibility of the operating management are included. Medical exposure is predominantly that of patients but also includes exposures incurred by those caring for patients, other than as part of their occupation, and exposures incurred by volunteers as part of biomedical research programmes, where there is no direct benefit to the volunteer. Public exposure then incorporates all exposures other than medical and occupational.

The principles of justification and optimisation apply universally to all three categories of exposure situations (planned, emergency and existing), whereas dose limits, apply only to planned exposure situations. The exception to this is planned exposure situations involving medical exposure where dose limits do not apply. In the absence of a dose limit, dose constraints assume a particular importance.

Dose constraints are used as part of the optimisation process for planned exposures. They represent a level of individual dose which should not, in normal circumstances, be

exceeded. They are used in the planning process and the chosen value will depend on the circumstances of the exposure under consideration. They are not a limit and do not represent a demarcation between safe and dangerous levels of radiation exposure but are used, prospectively, as a tool for optimisation. For planned exposures that have a dose limit associated with them, dose constraints should be lower than the pertinent dose limit.

The term practice was first introduced in 1991 in the publication ICRP 60 (ICRP 1991) to distinguish between an activity that added doses and one that reduced doses. The latter was known as an intervention. While the ICRP in their more recent publication ICRP 103 (ICRP 2007) have moved to a situation-based approach, as outlined above, they still use the term 'practice' to denote an activity that causes an increase in exposure to radiation or in the risk of exposure to radiation. It is implicit in the concept of a practice that the radiation sources that it introduces or maintains can be controlled directly by action on the source. It is understood, within the ICRP system of radiation of protection, that justification is a prior requirement of any new practice.

Although ICRP revised and updated their recommendations on radiation protection in their 2007 document, ICRP 103, current European legislation is still based on the recommendations contained in their earlier document, ICRP 60 (ICRP 1991).

3.2.2. Justification of practices

The justification of practices, involving ionising radiation, prior to their introduction into routine use, must demonstrate economic, social or other benefits in relation to the health detriment they may cause. Depending on the type of practice under consideration, this justification process can be complex and may involve consideration of a wide range of societal and economic factors, in addition to the potential dose detriment. The consequences to be considered are not confined to those associated with radiation; they also include other risks as well as the costs and benefits of the activity. Sometimes the radiation detriment will be a small part of all factors considered and it is important that other types of detriment are considered. Similarly, benefit must be determined. Justification therefore goes far beyond the scope of radiological protection.

Responsibility for judging the justification of new or existing practices usually falls on national radiation protection authorities to ensure an overall benefit in the broadest sense to society although not necessarily to the individual. However, these authorities are likely to need input from other stakeholders so that a fully informed decision can ultimately be made in relation to justification. To search for the best of all the available alternatives is a task beyond the responsibility of radiological protection authorities (ICRP 2007).

Although the justification process considers the potential benefits and detriments to the exposed individual and to society, a practice may be considered to be justified even if there are no benefits to the individual provided the benefit to society is sufficiently strong. Application of the justification principle to a new practice requires that no practice should be introduced unless it produces sufficient net benefit to the exposed individual or to society to offset the radiation detriment it causes. The justification may need to be re-examined as new information or technology becomes available.

This principle of balancing benefit and detriment is not unique to radiation safety but while often the balancing is done implicitly, the justification process will require an explicit demonstration of a net benefit.

The fact that the doses arising from a practice may be well below the public dose limit does not remove the requirement for justification or optimisation.

3.2.3 Legislative framework

In the European Union, radiation protection legislation relating to ionising radiation derives from the EURATOM Treaty. Its common objective is to establish uniform safety standards to protect the health of workers, patients and of the general public and to ensure that they are applied. The specific requirements for radiation protection are laid down in Title II Chapter 3 "Health and Safety", Articles 30 to 39 of the EURATOM Treaty. This system has been embodied in various European Directives most notably the Basic Safety Standards (BSS, originally adopted in 1959 and last revised by Council Directive 96/29/EURATOM) and the Medical Exposure Directive (MED, 97/43/EURATOM).

The BSS lays down the requirements for the protection of the health of workers and the general public against the dangers of ionising radiation. It encapsulates the principles of justification, optimisation and dose limitation and applies them to the regulatory system that controls practices involving ionising radiation. The scope of the Directive is wide and incorporates requirements for the reporting to the Competent Authorities of a wide range of practices involving the use of ionising radiation and for prior authorisation of many of these practices. The BSS sets dose limits for workers and members of the public and requires that workplaces are organised in a way that delineates and controls areas according to risk of exposure. The dose limitation requirement does not apply to three distinct groups of individuals exposed as a result of the use of ionising radiation in medicine – patients, persons knowingly and willingly helping patients (but not as part of their occupation) and volunteers in (bio)medical research. The BSS specifies the dose limit for workers as 100 mSv in a consecutive five-year period, subject to a maximum effective dose of 50 mSv in any single year. For members of the public, the limit is 1 mSv per year.

The Medical Exposure Directive (MED) deals with the health protection of individuals against the dangers of ionising radiation in relation to medical exposure. This Directive replaced the Patient Directive (84/466/EURATOM) and is the main legal instrument dealing with the protection of patients undergoing diagnostic and therapeutic procedures which utilise ionising radiation.

The MED aims at eliminating the practice of unnecessary medical exposures and to this end the principle of justification is central to the Directive. Justification and optimisation are seen as key in implementing radiation protection in medicine. The scope of the Directive includes not only patients but also other individuals exposed either directly or indirectly. This includes those exposed in occupational health surveillance, health screening, research and medico-legal procedures. Passenger security scanning using ionising radiation is not addressed explicitly in the current text of either the BSS or the MED. However, it has been considered in the context of the revision of the BSS which is currently under discussion.

Since the first BSS Directive was adopted, in 1958, it has been updated many times. The latest update was in 1996. A further revised and updated version was submitted as a Commission proposal to the European Parliament and the Economic and Social Affairs Committee in September 2011. In addition to the BSS, the proposal incorporates a revised version of the MED along with a number of other Directives which deal with radiation safety. The proposal and the opinions of the bodies mentioned above will be further considered by the European Council prior to adoption of a revised Directive. The following section describes the current requirements and the proposed revisions of the requirements are described in section 3.2.2.3.

3.2.3.1 Medico-legal procedures

The MED defines medico-legal procedures as 'procedures performed for insurance or legal purposes without a medical indication'. In including medico-legal exposures within the scope of the MED Directive, the objective was to ensure that persons presenting for medico-legal procedures were afforded at least the same level of protection as patients.

Medico-legal procedures were originally envisaged to be X-rays for insurance purposes and X-rays arising as a result of legal proceedings. In fact, the definition of medico-legal procedures is such that the scope is almost certainly wider. As a consequence, the range of exposures that might be considered to be medico-legal is both broad and diverse, extending beyond those performed for insurance or as a result of legal proceedings. Exposures arising from the use of security scanners for screening purposes fall under the broad category of medico-legal exposures.

Until such time as existing legislation is revised, the provisions within the Medical Exposure Directive apply. Article 5.4 of this Directive requires Member States to ensure that procedures are put in place that should be observed in the case of medico-legal exposures. The Directive also requires that special attention be given to the justification and optimisation of such exposures (Art 3.1 (d)).

Although medico-legal exposures are considered to be a sub-set of medical exposures, unlike medical exposures that are regarded as exposure of individuals as part of their own medical diagnosis or treatment, medico-legal exposures are not exempt from the public dose limit (96/29/EURATOM, Article 6.4). Therefore the dose limits set out in the BSS, for a member of the public, apply and so the limit for effective dose as a result of medico-legal exposures, such as security scanning, is that applicable to a member of the public. The categorisation of exposures to staff that are required to be screened (airline crews, airport workers, couriers, and others) as part of their occupation is less clear. The current thinking within the ICRP seems to indicate that these will be considered as public exposures rather than occupational and if this is the case then the public dose limit will apply.

3.2.3.2 Legal requirement for justification

The justification of practices involving ionising radiation prior to their introduction into routine use is a legal requirement enshrined in the BSS and the MED. The BSS requires Member States to ensure that all new types of practices are justified by their economic, social or other benefits in relation to the health detriment they may cause, in advance of being first approved.

In relation to justification, the BSS requires an explicit demonstration of a positive net benefit before a practice can be authorized by the regulatory body. As discussed in section 3.2.2., justification is likely to be a complex task and Member States will require some mechanism to ensure that an appropriate level of consultation takes place, commensurate with the radiological and social significance of the type of practice, before it can be considered to be either justified or unjustified.

The justification process may result in particular requirements being applied to these practices. Screening techniques, where the primary focus is security, could also be used to detect other contraband, such as illegal drugs, on a person. However, in the case for justification, the applicant should identify the primary purpose for introducing the technique to the Justifying Body and address issues that may arise that are not pertinent to the primary purpose.

The fact that the doses arising from the use of screening for security purposes may be well below the public dose limit does not remove the requirement for justification. In addition, for practices that are justified and subsequently authorised, optimisation measures must be taken so that all exposures are as low as reasonably achievable (the ALARA principle) for workers, the general public, and the population as a whole.

3.2.3.3 Revision of legislation

The European Commission has undertaken the simplification of Community legislation in the area of radiation protection and has proposed the consolidation into a single text of

five Directives. The main Directive is the BSS. The remaining four Directives cover different specific aspects of radiation safety complementary to the overall BSS. This includes health protection during medical exposures (97/43/EURATOM), the control of high activity sealed sources (2003/122/EURATOM), communication issues in an emergency situation (89/618/EURATOM) and the protection of outside workers (90/641/EURATOM).

One of the most significant changes in the revised Directive is in the way exposures previously classified as medico-legal are dealt with. Those exposures have been redefined as 'non-medical imaging exposure' and have been put under appropriate regulatory control. The new definition includes 'any deliberate exposure of humans for imaging purposes where the primary motivation for the exposure is not related to the health or well-being of the individual being exposed'. The need for justification of such practices, in three stages as for medical exposures, and for establishing associated conditions, has been worked out, including the differentiation between procedures implemented by medical staff using medical equipment and procedures implemented by non-medical staff using non-medical equipment, as in security screening.

The BSS annual dose limit and corresponding constraints for public exposure apply, while allowing for some exceptions for some specific non-medical exposure procedures carried out in a medical environment such as drug searches within the body.

3.2.3.4 Implications of the Revised Directive for security screening of passengers

The revised Directive requires a system of authorisation for non medical imaging exposures, including security screening. The requirements for justification and optimisation have been strengthened. The Directive requires that, in addition to the initial justification of the practice, each particular application of a generally accepted type of practice be justified in advance. Each justification must also be periodically reviewed by the Competent Authority. The Competent Authority must ensure that requirements for the practice, including criteria for individual implementation, are established as appropriate in cooperation with other relevant agencies and professional bodies.

The Competent Authority is required to ensure that dose constraints are established for security screening and that these are set to ensure that annual doses to members of the public remain well below 1 mSv (see draft revised BSS, article 23.3c). This dose criterion is likely to be readily achievable, even for the most frequently exposed groups (air crews, couriers and frequent flyers).

The Directive requires that informed consent of the individual to be exposed is sought, although it does allow for exceptions where law enforcement bodies may proceed without consent, if that is permitted by national legislation. Finally, the revised Directive requires that where the exposure is routinely carried out for security purposes the screened individuals are provided with a choice of an alternative technique which does not involve exposure to ionising radiation.

3.3. Technology

Three types of security scanners have currently been developed for airport security use. These are X-ray units using backscattered X-rays, X-ray units using transmission X-rays and non-ionising radiation units (see table in Background). Each of these is described in more detail below. The information on the operating parameters and safety systems of the scanners has been obtained from a number of sources including the equipment suppliers and the UK Health Protection Agency reports written under contract to manufacturers, suppliers and potential users.

3.3.1. Backscatter

Backscatter radiation is the radiation that is reflected (scattered) from a material back towards the X-ray radiation source.

X-ray security units using backscatter radiation operate by exposing the subject to low energy X-radiation. This low energy radiation passes through clothing but is readily scattered by dense objects. Some of the radiation is scattered back into a series of radiation detectors, and creates an image of the subject's body, showing any items concealed under the clothing.

Backscatter X-ray systems use a narrow, pencil shaped beam that scans the subject at high speed in a horizontal and vertical direction. Large detectors are installed on the same side of the subject as the X-ray source. The person stands in front of the enclosure and is scanned by the X-ray beam, which has a typical cross-sectional area of approx. 25 mm^2. Usually the person is scanned twice, once from the front and then from the back. Sometimes lateral scans are also performed. Typical systems use an X-ray set operating at fixed peak voltage (kVp) and current (mA) settings. These are typically 50 kV and 5 mA. The total filtration to reduce the low energy component in the X-ray beam, which is ineffective in the detection mechanism, is in the range of 1 mm to 7 mm aluminium equivalent. The duration of a single scan can be up to 8 seconds.

Figure 1: A modern backscatter unit showing a passenger being screened.

3.3.2. Transmission

Transmission radiation is the radiation that passes directly through the person being examined. This radiation can be measured by a detection system placed on the side of the person opposite to the X-ray source.

Transmission X-ray security units use significantly higher X-ray energies than backscatter units to create a radiographic image of the subject. The image is similar to those used for medical purposes and shows the skeletal structure of the subject, on which can be seen any contraband items with sufficient X-ray absorption contrast, which the subject has swallowed as well as any weapons hidden on the body beneath the clothing.

Transmission X-ray systems generally use a vertical fan-shaped beam of X-rays and a linear array of detectors. The person stands between the X-ray tube and the detector array and is scanned by an X-ray beam having a typical width of approx. 2mm. The limiting quantity for the spatial resolution is the size of the detector elements. Typical systems use fixed settings: X-ray peak voltage in the range 140–220 kVp and current in the range 0.1 to 4 mA. Filtration is deliberately incorporated in the X-ray beam to reduce the quantity of low energy X-rays that do not have sufficient energy to contribute to the imaging process, but do add to the radiation dose received by the person.

The total filtration in the X-ray beam is generally in the range of 4 mm to 8 mm aluminium equivalent. This value includes the inherent filtration that is a consequence of the X-ray tube construction as well as the added filtration.

Some units have the capability to operate in either a “low dose” mode (160 kVp, 0.1 mA) or “medium dose” mode (160 kVp, 0.3 mA). The mode used depends on the dimensions of the subject and the nature of the items being searched for. The duration of the exposure is in the range 5 to 15 seconds, depending on the model of unit.

Figure 2 shows a modern transmission scanner unit, with the side panel removed to reveal the X-ray set. The X-ray beam originates from an X-ray tube mounted on one side of a conveyor unit that the person undergoing examination stands on. The conveyor system moves the person past the X-ray tube. X-rays are initiated at the start of the scan sequence. Sensors terminate the exposure once a person has passed through the unit. If no person is present or the sensor fails, X-rays are terminated after a maximum of 12 seconds (the time the belt takes to move from one end to the other).

Figure 2: A modern transmission unit with the side maintenance panel removed.

X-ray systems that use both backscatter radiation and transmitted radiation in a single scan procedure are also commercially available.

3.3.3. Non-ionising backscatter radiation

A range of scanners using non-ionising radiation are currently being developed and assessed for security screening purposes. There are two types of this technology. Active scanners emit radio waves to produce an image. Passive scanners detect natural radiation emanating from the person.

The main scanners in the active scanner category are millimetre wave scanners, which emit radio frequencies within the 24–30 GHz frequency range. The radio waves are transmitted from two antennae simultaneously as they rotate around the body. The wave energy reflected back from the body, or other objects on the body, is used to construct a three-dimensional image, which is displayed on a remote monitor for analysis. During a scan, the individual is exposed to an electromagnetic field for a time not exceeding 2 s. The published surface power densities measured during a scan are low and vary between 60 $\mu W/m^2$ and 640 $\mu W/ m^2$.

The established health effects associated with non-ionising radiation are limited to thermal effects, although uncertainty remains concerning long-term effects of extremely

low frequency (ELF) and radio frequency (RF) fields. Millimetre wave body scanners operate at outputs well below those required to produce tissue heating.

Passive systems detect the very low levels of non-ionising radiation that are naturally emitted from the human body or objects concealed on the body. These systems produce no radiation, either ionising or non-ionising and hence present no radiation hazard.

Non-ionising security scanners are not considered further in this report.

3.4. Safety systems

X-ray security units are designed and supplied with comprehensive and modern safety systems. The type of systems that are installed on a particular model will depend on whether the scanner is a backscatter unit or a transmission unit but will include most of the following:

1. Password control. The X-ray set can only be operated from the control console and the controls are password protected.
2. Warning lights. The units have clear warning lights that indicate the condition of the X-ray set. These lights normally consist of a green light that is illuminated when the power is switched on but no X-rays are being generated, and a red light that is illuminated when X-rays are being generated.
3. Emergency stop buttons. Buttons positioned close to the operator's position can be pressed to immediately terminate the generation of X-rays.
4. Access panel interlocks. Panels that can be removed to provide access to the X-ray set are interlocked to ensure that X-ray generation is terminated and cannot be initiated when a panel is removed.
5. Operational interlocks. These will terminate the generation of X-rays in the event of a range of fault modes, including operational software malfunction, failure of a warning light or failure of the conveyor mechanism in the case of transmission scanners.
6. Local shielding. Lead shielding is incorporated into the scanners to ensure that radiation dose rates at accessible locations outside the scanning area are very low.

These examples are not exhaustive and additional safety systems may be fitted, depending on the type of scanner. Consideration of the required safety systems is an optimisation issue, and will be part of the dialogue between the supplier and the regulator.

The American National Standard 'Radiation Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation', ANSI/HPS N43.17-2009, specifies the operational interlocks that must be fitted to each type of scanner, and also requires that the generation of X-rays is automatically terminated in the event of any malfunction or fault mode. This standard is not formally endorsed in Europe, but as similar equipment is likely to be used as in the US, compliance with the standard is assumed (at least until a European standard is introduced). Compliance is, however, the responsibility of the manufacturers, unless required by the airport or travel safety authority upon purchase. Insufficient data are available to estimate the probability of any malfunction occurring, but the required interlock systems will ensure that, in the event of a malfunction, radiation doses to the person being scanned, the operators and any other persons in the vicinity will remain low.

3.5. Dosimetric aspects

To evaluate the risk contribution from scans performed with security scanners based on technologies using ionising radiation as described in chapter 3.3.1 and 3.3.2, it is necessary to describe the amount (doses) of ionising radiation received by the passengers. To do so it is important to clarify the various terms used.

3.5.1. Dose concepts

When dealing with ionising radiation, the basic concept used to describe the energy deposition caused by the radiation to any kind of material is the quantity "absorbed dose" D. This is defined as the energy E imparted into a small amount of material:

$D = dE/dm$

where m is the mass of material.

This dose is a pure physical descriptor of energy transfer due to the ionising radiation. The values of the measurements are given in the SI unit Gray (Gy) which is J/kg.

This physical parameter is in general not sufficient to describe the biological effects caused by ionising radiation. To take into account this dependence of the biological effects on the radiation type (alpha, beta, gamma, etc.) and energy, a weighting factor for the radiation quality w_R (ranging from 1 to 20) has been introduced and an additional dose term has been implemented for radiation protection purposes. This is the quantity "equivalent dose" H and is defined as:

$H = w_R * D$

The SI unit for the equivalent dose is the Sievert (Sv), which is also expressed in J/kg.

The security scanners using ionising radiation that are commercially available utilise X-rays with 50 kVp to 220 kVp(with some additional filtering) which have a nominal radiation quality factor $w_R = 1$.

One can distinguish between doses determined for specific persons (personal dose) and doses measured or assessed at specific locations (ambient dose).

3.5.1.1. Organ doses

First of all, in most applications of X-rays on humans, in circumstances of non uniform radiation as for example a chest X-ray, the equivalent dose to each organ might be different. As most epidemiological data refer to studies of external radiation exposures with quite high energies in large homogeneous fields, in these investigations one can assume a uniform dosage to the whole body. The security scanners, at the low energies of the ionising radiation used, will result in different doses to different organs. As the energy imparted decreases, so does the penetration and therefore the differences between the various organ doses is greater. There may even be differences within single organs. One assumes that the risk related to the dose in the same tissue is described by the average energy imparted multiplied by the radiation quality factor in the specific organ. Therefore the organ doses are given by the average of the equivalent dose over the whole organ H_T. These averages have to be determined for all organs.

$H_{T,R} = w_R * D_{T,R}$

3.5.1.2. Effective doses

Large epidemiological studies on the risk of ionising radiation, especially the life span study of the atomic bomb survivors of Hiroshima and Nagasaki, have shown that different organs show a different risk of stochastic effects like cancer development

caused by ionising radiation (see Epidemiology section 3.6.3). Based on morbidity and mortality data on the survivors and their basically uniform irradiation, specific risk coefficients have been determined for various organs. Assuming that the sum of the potential risks for all individual organs should represent the total risk of the total body irradiation then resulted in the approach of the effective dose E, where the risk coefficients are transferred to tissue weighting factors w_T for organs. By multiplying these risk factors with the corresponding equivalent organ doses and summing up the resulting weighted organ doses, one gets a dose describing a probability of health detriment comparable to a total body dose.

Effective dose is defined as:

$E = \Sigma_T w_T * H_{T,R}$

This dose value is not intended for the determination of a risk for an individual but is only an estimate of the average risk in a population even though the risk for an individual may vary due to age at exposure, gender or other risk factors.

The tissue weighting factors are listed in various ICRP (International Commission on Radiological Protection) publications. According to the actual determination of the ICRP the risk factors are as tabulated in Table 1 (from ICRP publication 103 (ICRP 2007)). Dose limits in legislation are expressed in effective doses and equivalent doses.

Table 1: Tissue weighting factors according to ICRP 103 (ICRP 2007)

Tissue	Tissue weighting factor wT	Σ wT
Bone-marrow (red), colon, lung, stomach, breast, remaining tissues(*)	0.12	0.72
Gonads	0.08	0.08
Bladder, Oesophagus, Liver, Thyroid	0.04	0.16
Bone surface, Brain, Salivary glands, Skin	0.01	0.04
	Total	1.00

(*) Remaining tissues: Adrenals, extrathoracic region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate (♂), small intestine, spleen, thymus, uterus/cervix (♀)

3.5.1.3. Specific doses

Regarding the use of the various scanners, doses to the skin and some other organs are of specific interest because of the non-homogeneous exposure due to irradiation geometry and the low energy of the radiation involved.

For the determination of organ doses some measurements are required. For risk assessment, equivalent doses are assessed. They are typically evaluated either as H*(10), which describes a personal equivalent dose measured at 10 mm depth of a reference sphere consisting of soft tissue equivalent according to the ICRU. For a close representation of the skin dose, H*(0.07) is used, which represents the equivalent dose value at a depth of 70 µm.

In the backscatter systems with relatively low photon energies (low radiation beam qualities) the organs close to the body surface such as the lens of the eye, the female breast or the testes will receive higher doses than organs deeper in the body. In systems using higher beam qualities (higher tube voltages, harder filtration) the dose distribution within the bodies would be more uniform.

3.5.2. Dose determination

Since it is difficult to measure doses of ionising radiation directly within the body, organ doses are typically evaluated by measuring doses on representative areas and then performing simulations using models of the human body. These simulations typically provide conversion factors to obtain organ doses from the measured entrance dose values. Historically, the first simulations were done on simple geometric mathematical phantoms. This has been the case for some studies already published; other studies provide dose measurements. These measurements are summarized in Table 2.

Table 2: Measured effective doses for various security scanners

Study	Effective dose per scan
Radiation Safety Assessment of the AIT84 Personnel Security Screening System. Occupational Services, Inc. USA, 2011 (a dual backscatter scanning system)	35 nSv
Supplier A Transmission unit A	3.8 µSv (*)
Supplier B Transmission unit B	261 nSv(*)
Supplier C Transmission unit C	4.2 µSv(*)
Supplier D Dual mode transmission unit	Low dose setting: 90 nSv(*) Medium dose setting: 332 nSv(*)
Supplier E Backscatter unit	19 nSv(*)

(*) Summary of measured doses quoted in contract reports from the UK Health Protection Agency provided to manufacturers/suppliers

Voxel phantoms with realistic anatomy were then produced. The new standard reference phantoms representing the standard man and the standard woman were introduced in ICRP publication 110 (ICRP 2009). Some conversion factors have already been determined for these new reference phantoms. Exposure of an average person in the context of a security scanner can be simulated. These simulations certainly do not take into account the variations between different persons. The determination of organ and effective doses for the average person is sufficiently accurate in view of the inherent uncertainty related to the low doses typical for security scanners.

The Monte Carlo simulations were performed on the new ICRP standard voxel phantoms of the human body used for the calculations were "RCP-AM" and "RCP-AF" (ICRP 2009)and on "Katja", the phantom of a pregnant woman in the 24th week of gestation (Becker *et al* 2007, Becker *et al* 2008). For the calculations, some simplifications about the geometry of the scanning process have been made. These should be conservative and of minor importance for the resulting effective and relevant (important organs and those with higher doses compared to other organs) organ doses. The determined values

(always for two sided (ap/pa) scans) are summarized in Table 3. The complete table can be found in the appendix.

Table 3: Modelled organ equivalent doses from backscatter scanners

	Organ equivalent dose (μSv)					
	Combined backscatter/transmission scanner			Backscatter scanner		
	RCP-AM[1]	RCP-AF[1]	Katja[2]	RCP-AM[1]	RCP-AF[1]	Katja[2]
Thyroid	0.248	0.264	0.443	0.045	0.047	0.046
Urinary bladder wall	0.115	0.203	0.177	0.020	0.034	0.017
Breast, total	0.269	0.239	0.410	0.021	0.045	0.045
Eye lenses	0.514	0.390	0.686	0.060	0.071	0.069
Lymphatic nodes	0.165	0.172	0.169	0.036	0.031	0.028
Muscle tissue	0.189	0.182	0.148	0.009	0.034	0.033
Ovaries		0.083	0.050		0.013	0.012
Skin, total	0.398	0.418	0.382	0.089	0.091	0.091
Testes	0.257			0.047		
Foetus total body			0.122			0.012
Effective dose	0.139		(0.160)	0.025		(0.022)

[1]ICRP 2009 [2]Becker et al. 2007, 2008

The radiation dose from a single passenger being scanned is approximately equivalent to natural background radiation received within an hour on the ground or during 10 minutes of flight at a typical cruising altitude (about 10,000 m).

It should be noted that an effective dose for the pregnant woman model is not really meaningful but given to allow a certain possibility of comparison. The dose values presented here are in the same range as those presented by most other publications.

Different studies have shown consistent results in terms of measured radiation doses for similar equipment. Furthermore, agreement between measured doses and doses calculated through simulations is good. However, a recent paper (Rez et al. 2011) estimated doses to the skin as high as 2.5 μGy for 50 kVp X-rays and 0.68 μGy for 50 kVp X-rays (effective doses of 0.9 and 0.8 μSv, respectively). Those results were, however, based on an approach different from the other studies (number of quanta needed for achieving image quality properties, with uncertain assumptions on geometry and signal-to-noise ratio likely to heavily influence the results). The Working Group concluded that the mainstream of the empirical studies is more likely to provide accurate dose estimates than the single outlier.

One should state here, that it is very difficult to give reliable and meaningful estimates of effective doses for children up to the age of at least 14 years, since the variations in stature and size are even greater than for adults. In addition, there is still no reference set of real anatomy based voxel phantoms representative of the various sizes of children. Besides which, the effect of geometric proportions of the child to the scanner and the mode of use of the scanning would result in large variations. It should be reasonable to

assume that the effective doses would be in the same order of magnitude as those of the adults.

3.5.3. Special groups

There is some variability in the effective dose from body scanners between individuals in relation to their physical characteristics (body size and gender). Therefore, the calculated dose values only indicate an average of doses due to the use of security scanners. The range of doses to an adult may vary by up to a factor of two.

For risk assessment purposes it is necessary to identify the population group or groups that are anticipated to receive the highest exposure. The groups likely to be scanned frequently include frequent flyers, couriers, air crews and airport staff. Tto assess the maximal plausible dose from security scanners, it is assumed that someone flying each working day of the year with several connecting flights might be scanned three times daily with a total of up to 720 times annually (such frequent exposure is unlikely, as normally transit passengers do not need to be scanned between connecting flights at the transfer airport). The cumulative effective dose from a backscatter scanner would thus amount to roughly 300 μSv (assuming a dose of 0.4 μSv per scan, i.e. higher than the typical values estimated). If all scans were performed using transmission technology (assuming an effective dose of 4 μSv per scan), the corresponding annual cumulative effective dose would be one order of magnitude higher, approaching 3000 μSv or 3 mSv. This would clearly exceed the dose limit for the general public (which is applicable to the passengers, but also to other frequently scanned groups such as airline crews, airport personnel, etc). The principle of dose limitation would therefore indicate a preference for backscatter technology, unless the capacity to detect objects within the body is deemed crucial.

Sensitivity (susceptibility to harmful effects) varies also within the population in relation to age, sex and other factors. Potentially sensitive groups within the population include pregnant women (foetuses) and children. This is addressed in section 3.6.3.

3.6. Health effects

3.6.1. Types of health effects

Deterministic effects (or tissue reactions) of ionising radiation are related directly to the absorbed radiation dose and the severity of the effect increases as the dose increases. A deterministic effect typically has a threshold (of the order of magnitude of 0.1 Gy or higher) below which the effect does not occur. Deterministic effects are based on tissue damage.

However, deterministic effects of ionising radiation do not need to be considered as a health hazard at the low doses delivered by X-ray scanners based on the threshold dose recommendation in ICRP publications 60 and 103 (reviewed in ICRP 2011 and Wrixon 2008) - that 'in the absorbed dose range up to around 100 mGy (low LET or high LET) no tissues are judged to express clinically relevant functional impairment. This judgement applies to both single acute doses and to situations where these low doses are experienced in a protracted form as repeated annual exposures'. According to ICRP publication 103 (ICRP 2007), the threshold for deterministic effects following pre- and post-natal exposure is proposed to be >100 mGy and this judgement for acute doses has been ratified by ICRP (document in consultation 2012). Radiation-induced malformations are considered by ICRP publication 103 (ICRP 2007) to have a dose-threshold of ~100 mGy.

Lens opacities induced by ionising radiation have been traditionally regarded as a deterministic effect with a threshold exceeding 1 Gy. Recently, several studies have

demonstrated lens opacities at dose levels around 100 mSv, but extrapolation down to µSv dose level would not be meaningful.

Stochastic effects of ionising radiation are chance events, with the probability of the effect increasing with dose, but the severity of the effect is independent of the dose received. Stochastic effects are assumed to have no threshold. Primarily cancer risk, but also hereditary disorders are stochastic effects with a combined detriment of ~5%/Sv (ICRP publication 103 (ICRP 2007)). Hereditary effects of radiation (germline mutations induced by radiation that are transmitted to the offspring and may result in congenital anomalies or increased risk of common multifactorial disease) are not considered here, because they have not been observed in human populations with higher doses (and any theoretical risk would be obscured by the vastly higher spontaneous mutation rate).

3.6.2. Biological effects

3.6.2.1. Shape of dose-response curve – targeted effects, radiation induced cellular DNA damage

DNA double strand breaks (DSB) play a critical role in the carcinogenesis process. DSB induced by low Linear Energy Transfer (LET) radiation in mammalian cells shows a linear dose dependence down to the lowest measured dose of 1 mGy (Leatherbarrow et al. 2006, Rothkamm & Löbrich 2003) and *in vivo* to doses as low as 100 mGy (Löbrich 2005). The shape of the dose-response curve is in support of the Linear No Threshold (LNT) model (most recent ICRP publication 103 (ICRP 2007)) down to the lowest experimental doses of 1 mGy. The shape of the dose dependence curve for DNA damage induction at doses much lower than 1 mGy is unknown. Therefore, the present assumptions on the use of LNT for radiation protection are based on the linear extrapolation and the inability to measure biological changes at doses of a few µGy.

The repair of DSB after a dose of 1 mGy in human fibroblasts and in tissue samples from 10 mGy irradiated mice is compromised even up to 24 h post-irradiation, whereas at higher doses DSB rejoining occurs (Grudzenski et al. 2010). At these low doses, a single DSB will only be formed on average in ~1 in 20-30 of the cells exposed, with even fewer formed (<1 DSB per 2-3 x 10^4 cells) at doses of a few µGy, unless as yet unknown processes occur at ultra-low doses. Based on the present knowledge and the inability to measure biological changes at doses of a few µGy, the present assumptions based on the LNT model for radiation risk estimate remain valid.

Experimental data (Nakano et al. 2007) indicating that chromosomal aberrations do not persist after *in utero* irradiation with a dose of 1-2 Gy may also relate to the recent epidemiological data finding that pre-natal exposures are of lower risk.

Although the relative biological effectiveness (RBE) for various end points, based on *in vitro* cellular radiobiology, increases with decreasing photon energy relative to ^{60}Co gamma rays at doses >1 Gy (Hill 2004), these findings question the recommended use of a w_R value of 1 for all photon energies as recommended in ICRP publication 60 (ICRP 1991). However, it was concluded from epidemiology studies that it is not statistically feasible to draw any conclusions of an underlying dependence of cancer risks for thyroid or breast on LET for radiation with photon energies less than that for ^{60}Co-radiation (Hunter and Muirhead 2009). The epidemiological findings are compatible with the use of a w_R value of 1.

3.6.2.2. Non-targeted effects

New findings on non-targeted effects such as bystander effects and genomic instability could affect the LNT model. The European Integrated Project NOTE (2006 – 2010)

addressed whether the effects of ionising radiation, characteristically associated with the consequences of energy deposition in the cell nucleus, arise in non-irradiated cells and are relevant for the use of the LNT model in extrapolation to low dose to estimate risk (the final report is available from:

https://ssl.note-ip.org/documentindex.asp?id=3089&type=1&show=1).

The majority of the studies were carried out at doses of 10 mGy or higher. Taking into account concerns relating to the LNT model of radiation protection recommended most recently in ICRP publication 103 (ICRP 2007), it was concluded from the NOTE studies that no compelling evidence for non-targeted effects requires modification of the LNT model for risks to human health. Based on present knowledge of non-targeted phenomena, their incorporation into radiation protection for sparsely ionising radiation (such as X-rays used in both types of security scanners using backscattered or transmission X-rays) is premature in the absence of direct evidence of relevant health endpoints (Averbeck, 2010, Goodhead 2010). The majority of non-targeted effects have only been seen at doses >1 mGy for low LET radiation.

3.6.2.3. *In vivo* models

Animal models are well established methods for improving understanding of ionising radiation induced carcinogenesis. To date the majority of findings on radiation carcinogenesis using mouse models have been obtained at high doses of low LET radiation with a few studies using doses extending down to around 50 mGy (Munley et al. 2011, Pazzaglia et al. 2009). The incidence of tumorigenesis on radiation dose is linear in the range 50-500 mGy (Pazzaglia et al. 2009, Shuryak et al. 2011). A direct dose rate effect was seen with reduced incidences for a dose rate of 0.01 Gy/day (Shuryak et al. 2011). The radiation doses used in this study are about 10 times greater than those estimated for a human scan with a backscatter scanner. As for the epidemiology data with animal models in the mGy range, large numbers of animals are required to obtain statistically significant data. Additionally the incidence of carcinogenesis at the lowest doses around 50 mGy approaches the spontaneous levels in these mouse models. Data from animal models are not available in the µGy range.

3.6.3. Epidemiology

Epidemiological evidence regarding the health effects of low-dose radiation has been obtained from numerous studies since the mid-20th century. Studies informing about health risk from radiation have covered various sources and circumstances of exposure, including environmental, medical and occupational radiation exposures. Population-level studies in humans have demonstrated a dose-dependent increase in cancer risk, with consistent findings in different populations. Ionising radiation can induce most, but not all cancer types. The latency from exposure to the occurrence of excess cancer is typically approximately one decade, but shorter (2-5 years) for leukaemia and thyroid cancer. The elevated risk appears to persist several decades.

In ICRP publication 103 (ICRP 2007), the cancer risk for prenatal exposure was judged to be similar to that following irradiation in early childhood. However, recent evidence (Preston et al. 2008) indicates that the lifetime risk of developing solid cancers (but not leukaemia) following *in utero* exposure to ionising radiation, while higher than that seen for exposure in adulthood, is considerably lower than that for exposure in childhood, i.e. at most, about three times that of the population as a whole.

The disease risk caused by radiation can be expressed in terms of relative risk (RR), i.e. as a multiple of the underlying disease risk. A RR of 1 indicates a similar occurrence in the study population as in the reference group, while for instance a RR of 1.5 shows a relative increase by 50% (i.e. 1.5-fold occurrence). Such a relative risk model inherently assumes that the health effect is proportional to the baseline risk of the population, i.e. whether the disease risk due to other factors such as age is low or high, the exposure

would always increase it as a multiple of the baseline. Alternatively, an absolute risk model can be used to depict the effect of an exposure with a given increase in occurrence. Here, a constant absolute increase in risk is assumed, independent of the baseline risk. As an example, a cohort study might report cancer incidence of 150 per 100,000 person-years in an unexposed group and 200 per 100,000 among subjects with radiation exposure. The relative risk (rate ratio) for the exposed cohort is then 1.33 (200/150), while the absolute risk (excess incidence) is 50/100,000 (200/100,000-150/100,000). Adopting a relative risk model would imply that the effect of a similar exposure in any other population would result in 1.3-fold increase, whereas extrapolation using an absolute risk (or absolute effect) model would predict an increase by 50/100,000.

The major sources of uncertainty in these studies have included exposure assessment (dosimetry), exposures from other sources, and effects of other factors on disease risk (confounding). Typically, the highest quality dose estimates have been available for studies assessing the effects of medical uses of radiation and the lowest for studies on environmental exposures. On the other hand, other sources of uncertainty can play a large role.

Uncertainty can be divided into two types: stochastic and epistemic. Stochastic uncertainty is related to the observations available and can be reduced by increasing the amount of data. Statistical variability or random error is an example of stochastic uncertainty. Epistemic uncertainty pertains to models and assumptions involved in interpreting the data. It is not related to the amount of observations. For instance, the validity of an experimental model is typically epistemic uncertainty. If for instance DNA breaks are not essential for cancer risk from ionising radiation, conducting more studies using such an approach will not improve the knowledge due to epistemic knowledge being a limiting factor.

Stochastic uncertainty, i.e. random error, is a limitation of the ability of the epidemiological studies in particular when dealing with small effects. Random error is the variability unrelated to exposure of interest and can be thought of as the background noise against which the phenomenon of interest needs to be distinguished. The capacity to demonstrate either the presence or absence of an effect is called statistical power. It depends on the amount of information available, which is related to the study size, exposure distribution and disease risk. Roughly, the higher the number of events and the more evenly they are distributed across the compared groups, the higher the statistical power.

Besides random error, the quality of the results of a study depends on systematic error, i.e. bias and confounding. Bias is distortion of information that (unlike random error) is related to the phenomenon under study, either exposure (potential determinant of disease risk studies) or the outcome (disease status). The major types of bias are information bias and selection bias. The former has to do with the availability or quality of information (differences in extent or quality of exposure data between those with and without the health outcome, or differences in outcome data between exposure groups). Selection bias occurs when the inclusion in the study differs from the ideal or intended in such a way that it distorts the comparability of the groups within the study. Selection bias can occur if two groups differ from each other in terms not only of exposure being studied, but also of other factors affecting the disease outcome. The so-called healthy worker effect is an example of selection bias. Healthy worker bias occurs due to the fact that employed people have generally better health than those who are not working (as some of them may have retired due to an illness, or their health may have deteriorated because of unemployment), which results in lower mortality in several occupational groups compared with the general population. Also, patients undergoing medical interventions such as diagnostic X-rays or radiotherapy may differ from the healthy subjects in terms of risk of cancer or other diseases (because they are selected for the intervention based on a suspected or diagnosed health condition).

Confounding is the distorting effect that other risk factors may cause on the exposure-outcome relation of the studies. For example, studies on areas with elevated rates of background radiation may suffer from confounding if the population in other nearby areas that they are compared with differs also in other respects such as lifestyle factors relevant for cancer risk (e.g. smoking, diet, physical activity, infections etc.).

The single most important source of epidemiological knowledge on health effects of radiation has been the Life Span Study of the atomic bomb survivors in Hiroshima and Nagasaki. A wide range of doses (from several Sv down to 5 mSv), good quality dose estimates, a large study population covering a wide age span and long follow-up with information on both cancer incidence and mortality increase the amount and quality of evidence from the study. Among atomic bomb survivors, a significant dose-response relationship is seen in the dose range 0-150 mGy for solid cancers and the existence of a threshold (below which no effect is seen) can be excluded at 85 mGy or higher (but not below).

The effect of radiation on cancer risk is not uniform across the population; it is modified by some factors. First, cancer risk following radiation exposure at a young age is higher than for exposures later in life (although this effect can also be explained in terms of age attained). Exposure at a young age generally tends to result in a larger relative effect than at older ages. In the atomic bomb survivor studies, the excess relative risk per Gray (ERR/Gy) for all solid cancers decreased by 17% per decade of age at exposure (90% CI -25%, -7%). In terms of absolute excess risk, the decrease per one decade increment in age was -24% (90% CI -32, -16). Alternatively, the effect of age can be expressed in term of attained age, i.e. in relation to the risk at a given age during follow-up (age at observation), with an equally good fit with the observations. The cancer types where this effect is very pronounced include thyroid cancer, leukaemia and breast cancer. Also, the risk coefficients tend to be slightly higher for women than men. Among atomic bomb survivors, the ERR coefficients at 1 Gy for incidence of all solid cancers for women have been larger by a factor of 1.6 compared with men (ERR of 0.35/Gy for men and 0.58/Gy for women) (Preston et al. 2007). This may reflect more the difference in background rates than sensitivity to radiation effects. A smaller difference (female:male ratio of 1.4) is found in absolute excess risk (43 versus 60 excess cases per 1000 person-year-Gray), and it decreases further, when the gender-specific cancers (breast, prostate and gynecological) cancers are excluded.

Extensive research on cancer risk related to low doses of radiation (in the mSv range) received from occupational exposure, medical diagnostic procedures and in areas with an elevated natural background radiation has been conducted during the past decades. Some of the key findings are summarized in the following section.

A meta-analysis of leukaemia risk from low-dose exposures combined the results of 10 studies (mainly on occupational exposures) and showed a pooled risk estimate of ERR 0.19 (95% CI 0.07-0.32) per 100 mGy (Daniels and Schubauer-Berigan 2011).

A systematic review of cancer risk from diagnostic X-rays showed no clear excess from nine case-control studies of prenatal exposure published after 1990 (OR 0.99, 95% CI 0.87-1.13), though it did not include the early Oxford Survey (Schulze-Rath et al. 2008).

A recent large case-control study found no significant excess of all cancers (OR 1.14, 95% CI 0.90-1.45) or leukaemia (OR 1.36, 95% CI 0.91-2.02) associated with any diagnostic radiation *in utero* (Rajaraman et al. 2011). Also, a cohort study with 5,590 pregnant women who had been exposed to ionising radiation for diagnostic purposes showed no clear excess cancer incidence (RR 0.68, 95% CI 0.25-1.80 based on four childhood cancers) (Ray et al. 2010). A German cohort of more than 78,000 children who had undergone diagnostic radiographic examinations also showed no excess of childhood cancer (RR 0.97, 95% CI 0.75-1.23), or trend across dose categories (Hammer et al. 2011).

Studies in high natural background areas in India and China have not been able to show elevated cancer rates when comparing populations with annual doses of around 1 mSv

versus 4 mSv (and cumulative doses up to several hundred mSv) (Nair et al. 2009, Tao et al. 2012).

The results of these studies do not of course exclude the existence of a health effect in the mSv dose levels. They are indeed compatible with risk estimates from studies of higher doses and mainly indicate that risks at low doses are not materially larger than predicted from high-dose studies.

Epidemiological studies have not found major differences in health risks from ionising radiation between subgroups of the population defined by hereditary factors. Among patients receiving radiotherapy for retinoblastoma, a childhood tumour of the eye, those with the hereditary bilateral form of the disease have a higher risk of secondary sarcoma. Breast cancer patients who are carriers of the rare missense variant form of the ataxia telangiectasia gene have been shown to be at an increased risk of contralateral breast cancer following radiotherapy compared with other patients receiving radiotherapy for their first breast cancer.

Epidemiological studies have not provided consistent evidence regarding a lower risk from radiation exposure occurring over an extended period of time compared with similar doses received at higher dose rates. A pooled analysis of 12 epidemiological studies of occupationally exposed groups (Jacob et al. 2009) did not find evidence of lower cancer risk related to protracted rather than acute exposure.

The effects of ionising radiation on the risk of cardiovascular disease have been shown in the past 20 years. Radiotherapy at high doses (>10 Gy) to the heart increases the risk of cardiac disease, with radiation-related heart disease (such as pericarditis, valvular disease or cardiomyopathy as direct result of radiation) from the dose level of several Gray upwards emerging after a minimal latency of 1-2 years (although acute pericarditis may develop as soon as some weeks after). Among atomic bomb survivors, there is a dose-response relationship in late cardiovascular disease mortality, including both heart disease and stroke after at least a decade (Shimizu et al. 2010). Such effect could, however, be neither confirmed nor excluded at dose levels below 0.5 Gy. In some occupational cohorts an increased risk of cardiovascular disease in relation to radiation dose has also been suggested, but the possible effect of confounding has not been ruled out.

The strength of the epidemiological studies is their direct relevance for risk assessment – they deal with actual disease and exposure to agents as it occurs in real life without the need for extrapolation from species, dose levels or outcomes to another. Direct inference counterbalances the uncertainties usually encountered in epidemiological studies, particularly non-randomised studies.

The ability of epidemiological studies to demonstrate (or exclude) small health effects is limited by the uncertainties and sources of error outlined above. Common non-infectious diseases such as cancer and cardiovascular disease result from long multi-factorial processes. Such complex diseases have multi-factorial etiology. A malignancy caused by exposure to ionising radiation cannot be distinguished from tumours due to other factors. For instance (long-term occupational) radiation exposure with a cumulative dose of 200 mSv may result in 1.1-fold cancer risk. However, it is impossible to tell which of the cancers occurring in such a population are attributable to radiation and which are caused by other factors. The effects of very low radiation doses, say below 100-200 mSv, are very difficult to demonstrate in epidemiological studies. In order to put such small incremental risks in evidence, very accurate information on exposure (with minimal random error and bias) would be needed. In addition, exposure from other sources including natural background radiation would need to be known. Furthermore, the baseline risk due to other factors (confounding factors) would need to be very well characterized. Finally, comprehensive information on all disease cases should be available. In practice such ideal circumstances are not possible. Even in a very large study of 100,000 subjects followed up for cancer incidence for 10 years (after the 10 year latency period), the expected number of cancer cases might be of the order of

2,000. The effect of 100 mSv could be expected to induce 100 additional cases. Such a small increment would be easily missed due to random error – it can be calculated that if 100 such studies were carried out, only just over half (approximately 60) would be able to show an effect assuming that a comparable cohort of unexposed people was available (not considering bias and confounding).

3.6.4. Extrapolation to low doses

Overall, the doses from X-ray scanners are so low that the biological effects both in cellular and *in vivo* models cannot be experimentally determined or quantified. The dose is in the range classified as a negligible individual dose by NCRP Commentary N° 16 (NCRP 2003). The cumulative effective dose from a whole body X-ray backscatter scanner to a person who uses air travel daily is small relative to the control level of 0.25 mSv y^{-1} recommended by NCRP Commentary N° 16 (NCRP 2003).

In view of the low doses from security scanners there is no scientific basis to separately consider potentially vulnerable groups (e.g. pregnant women, children) in risk assessment. This is due to the much larger uncertainties in risk estimates relative to the variation of risk between subgroups of the population, i.e. even the potential of µSv-level doses to induce any health effects is uncertain, while the differences in risk between population subgroups are within one order of magnitude and demonstrable only at dose levels exceeding 100 mSv.

Recently, the United States National Academy of Sciences and National Research Council published an evaluation of health risks from low doses of ionising radiation (BEIR 2006). Based on atomic bomb survivor data on cancer incidence and mortality, complemented with data from medically exposed population for breast and thyroid cancer, risk predictions were made for doses below 100 mSv. A review of both biological and biophysical studies on mechanisms of radiation-induced cancer concluded that the cancer risk is likely to occur in direct proportion to dose (with a linear dose-response relationship) even at the lowest doses without a threshold, even if the risks would be very low. The life-time risk model developed predicts that for a radiation dose of 100 mSv, one additional cancer case (including both solid cancers and leukaemia) would be expected to occur per 100 exposed persons (against a background of 42 cases unrelated to radiation). Correspondingly, one additional cancer case would be expected per 1,000 people exposed to 10 mSv during their remaining lifetime. The number of excess cancer deaths due to radiation would be approximately half of the incident cancer cases.

Individual risk versus population risk has been proposed (Brenner 2011) as 'one of the means of assessing the acceptability of a facility or practice' by NCRP Commentary N° 16 (NCRP 2003). Probability of an adverse effect due to radiation exposure from whole body X-ray backscatter scans is likely to be of the same order as the negligible individual risk level (NIRL) of 10^{-7} y^{-1}, given in NCRP Report N° 91 (NCRP 1987) corresponding to an effective dose equivalent of 0.01 mSv. The recommendation in NCRP Report No. 91 (NCRP 1987) that assessments of increments of collective annual dose from any particular individual source or practice should exclude those individuals whose annual effective dose equivalent from such sources was ≤0.01 mSv was withdrawn by the NCRP and superseded by NCRP Report No. 116 (NCRP 1993). A negligible individual dose, defined as an annual dose value for a particular radiation source or set of sources is described in NCRP Report No. 116 (NCRP 1993). The negligible individual dose was set at 10 µSv, corresponding to the effective dose per scan from at least 50 whole body X-ray backscatter scans. NCRP Commentary No. 16 (NCRP 2003)recommended that the cumulative effective dose to an individual member of the public from such X-ray systems used in security screening of humans should not exceed a control level of 0.25 mSv y^{-1}, and for an individual scan the effective dose should be ≤0.1 µSv (discussed in Schauer 2011).

For an extremely small individual risk, Brenner (2011) suggested the population risk is also negligible but not zero, although it was acknowledged that many uncertainties exist in the estimation of individual risk. ICRP publication 103 (ICRP 2007) does not recommend the use of collective effective doses (population doses) over long time periods as an appropriate management approach to make decisions and in particular, the calculation of the number of cancer deaths based on collective effective doses from trivial individual doses should be avoided.

Some examples of health risk assessment related to low doses of radiation below the level, which can be directly observed in epidemiological studies are described below, even though these projections utilising theoretical calculations pertain to exposure levels higher than those received from body scanners. They suggest that radiation doses in the mSv range could be expected to increase the occurrence of cancer by an order of magnitude of 1%. As the radiation doses from body scanners are several orders of magnitude lower, the risks can also be assumed to be smaller.

To assess cancer risk attributable to radiology, Berrington de Gonzáles and Darby (2004), used linear excess absolute and relative risk models based on Japanese atomic bomb survivors. They took into account age at exposure (for breast cancer and leukaemia also age attained), frequency of diagnostic X-rays (nine types of radiographic, eight fluoroscopic and 10 CT examinations in 1991-96, with older British data on age and sex distribution of patients), organ doses and cancer incidence (specifically, leukaemia, and oesophagus, stomach, colon, liver, lung, bladder, and thyroid cancers) in 15 countries. Risks were projected for all other cancer sites (excluding lymphoma, multiple myeloma, and chronic lymphocytic leukaemia) assuming a similar risk coefficient. The estimated annual average radiation doses to various organs were below 1 mGy and projection carried out assuming that there is no threshold below which cancer risk would disappear. The results indicated that roughly 0.6% of the lifetime cancer risk in the UK might be attributable to diagnostic radiological examinations, with higher estimates for most other countries. More conservative assumptions regarding the duration of effect, mortality in the exposed patients relative to the general population and using a dose and dose-rate effectiveness factor (DDREF) of 2 decreased the effects by 10-50%.

The long-term impact of the Chernobyl fallout on cancer incidence was predicted by Cardis and co-workers (Cardis et al. 2006). They used both Excess relative Risk (ERR) and Excess Absolute Risk (EAR) models to project risks from doses of the order of 0.5 mSv received over 20 years time. The overall estimate was 0.01% increase in overall cancer incidence in Europe and 1.5% excess of thyroid cancer. The goal of the theoretical calculation was mainly to provide an indication of the order of magnitude of possible effect (2,400 cases in a population of 572 million over eight decades). The authors noted the need for caution when applying risk models developed based on different populations exposed to single high doses to circumstances of very low cumulative doses delivered over decades.

The contribution of background radiation to leukaemia risk was recently estimated. Based on annual doses of 1.2 mSv and the risk model derived by UNSCEAR from atomic bomb survivors, it was estimated that approximately 4% of all cases of leukaemia could be attributable to natural background radiation, and the proportion would be larger for childhood leukaemia (5-19%, depending on the risk model) (Kendall et al. 2011).

4. OPINION

This document is prepared in response to the request of the Commission and provides a summary of the scientific knowledge on the potential health effects of X-ray based security scanners for passenger screening. It is not intended to address the issue of justification, which remains a national prerogative, as specified in the relevant EU legislative framework for radiation protection. This framework specifies the requirements for use of all equipment using ionising radiation, including prior justification before a practice is introduced.

The justification for introducing a new practice, particularly outside the medical field, is a complex process and radiation protection considerations are only one aspect. In the use of X-ray security scanners for screening individuals, the benefit accrues primarily to society rather than to the exposed individual. The risk-benefit ratio should be considered in the justification prior to a practice being introduced but this may also need to be revisited when new technologies are introduced or new information becomes available.

Although the doses per scan arising from the use of screening for security purposes are well below the public dose limit, this does not remove the requirement for justification. In addition, for practices that are justified and subsequently authorised, optimisation measures must be taken so that all exposures are as low as reasonably achievable (the ALARA principle) for workers and the population as a whole.

The SCENIHR was asked:

> *1. To assess the potential health effects related to the use of all types of security scanners used for passenger screening which emit ionising radiation.*

To assess the maximal plausible dose from security scanners, it is assumed that someone flying each working day of the year with several connecting flights might be scanned three times daily with a total of up to 720 times annually

The radiation doses to screened passengers are very low compared with other sources (e.g. the cosmic radiation received during the flight) even after taking into account the likely number of scans received by frequent flyers. Therefore, the Committee concludes that there is no risk of deterministic effects (tissue reactions) associated with normal use of X-ray based security scanners at airports, because the doses delivered are, in any scenario, much lower than any known threshold above which deterministic health effects would occur. However, the possibility of stochastic effects (long-term effects such as cancer risks) cannot be entirely excluded. However, if such risks exist, they are orders of magnitude below the baseline (spontaneous) cancer risk due to other factors.

The radiation dose from a single backscatter scan is well below 1μSv (0.02 – 0.1) while that of a transmission scan is up to 5 μSv (0.1 – 5). This difference could result in significantly higher cumulative doses which may exceed the annual dose limit for members of the public if transmission scanners are used as routine screening devices for frequently exposed individuals (airline crews, frequent flyers, airport personnel, etc.). The higher doses used by transmission scanners must be given an emphasis in the justification process.

> *2. If any effects are identified under 1, to quantify the risks and, if feasible, to estimate the additional number of cases of diseases that are expected to occur in Europe due to the use of this technology at EU airports, differentiating between the general public and exposed workers as indicated below.*

The dose levels from the use of security scanners are well below the range where any health effects are observable. Due to the very low radiation doses to both scanned passengers and the exposed workers, any quantitative estimation of risk would be highly uncertain and rely on non-verifiable assumptions about extrapolations to dose levels

where health effects cannot be demonstrated. The risk assessment performed here relies on the linear no-threshold model according to which the probability of adverse effects is directly proportional to the radiation dose. The risk estimates are based on theoretical projections from observations at substantially higher exposure levels.

There is no sufficient scientific basis for making any quantitative risk estimates such as calculating the additional number of cancer cases induced by the introduction of security scanners at airports, either to the general public or the exposed workers.

In its assessment, the SCENIHR is asked to consider in particular the risk for populations that are regularly exposed to such technologies (e.g. frequent flyers (to be defined), air crew, security workers operating the scanners and other airport staff) and potentially vulnerable groups (e.g. pregnant women, children).

It has been proposed that all those screened including frequent flyers and airline crews are subject to the public dose limit of 1 mSv per year and only the personnel operating the scanners be considered as occupationally exposed from this source. Annual cumulative effective doses would remain below that level for backscatter technology even with highest plausible scan frequencies (three scans every working day of the year), but with transmission technology such a dose limit could be exceeded for individuals with such high scan frequency. Appropriate dose constraints for members of the public should be set at a substantially lower level than the public dose limit. While a suitable constraint of the order of 0.25-0.5 mSv would be very unlikely to be approached for most passengers who are scanned using backscatter scanners, it could potentially be exceeded by those persons who are scanned several times a day throughout the year (e.g. flight crew, ground staff), given a dose of 0.4 μSv per scan. Scanning of frequent fliers with X-ray transmission scanners could result in both the constraint and dose limit for members of the public being exceeded, assuming a dose of 4 μSv per scan.

In view of the low doses from backscatter security scanners there is no scientific basis to separately consider potentially vulnerable groups (e.g. pregnant women, children) in risk assessment. Cumulative doses are very likely to remain below the constraints with backscatter scanners even for frequently scanned individuals.

Use of transmission scanners could result in exceeding dose constraints for frequent flyers and certain occupational groups. An occasional transmission scan does not require separate consideration even for potentially vulnerable groups of the population.

The SCENIHR should compare the relative risk of such security scanners using X-ray based technologies to other security scanner technologies on the market.

The current scientific evidence does not allow for a direct comparison of various technologies because of the different nature of exposure for ionising and non-ionising radiation. There is no scientific basis for predicting stochastic health effects of passenger scanning technologies using non-ionising radiation such as mm wave or THz scanners. Furthermore, the thermal effects of exposure to non-ionising radiation are not cumulative and non thermal health effects are not proven. The use of these technologies has been shown to comply with exposure limits based on thermal effects (International Commission on Non-Ionising Radiation Protection - ICNIRP).

At the levels typical of X-ray based security scanners, only stochastic effects could occur, but the predicted probability of their occurrence is very low and there is no scientific evidence supporting their existence.

Passive devices that do not emit any radiation are not expected to have any adverse health effects.

5. MINORITY OPINION

None

6. LIST OF ABBREVIATIONS

BEIR	Biological Effects of Ionising Radiation
BSS	Basic Safety Standards
DDREF	Dose and dose-rate effectiveness factor
DNA	Deoxyribonucleic acid
DSB	Double strand break
EAR	Excess absolute risk
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EDPS	European Data Protection Supervisor
EFSA	European Food Safety Authority
ELF	Extremely Low Frequency
EMA	European Medicines Agency
ERR	Excess relative risk
ETD	Explosive trace detection
FRA	Fundamental Rights Agency
HHMD	Hand-hand metal detection
ICNIRP	International Commission on Non Ionising Radiation Protection
ICRP	International Commission for Radiation Protection
ICRU	International Commission for Radiation Units and Measurements
LET	Linear energy transfer
LNT	Linear no threshold
MED	Medical Exposure Directive
NIRL	Negligible individual risk level
NCRP	US National Council on Radiation Protection and Measurements
OR	Odds ratio
RBE	Relative biological effectiveness
RF	Radiofrequency
RR	Relative risk
SCCS	Scientific Committee on Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
WTMD	Walk-through metal detection

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ANNEX I – REPORT ON MONTE CARLO SIMULATIONS OF EXPOSURES WITH AIRPORT SECURITY SCANNERS

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Scanners

The calculations were performed for two scanners according to the specifications provided:

1. Combined backscatter and transmission scanner:

X-ray spectrum: Tungsten target, 14° anode angle, filtration 1.4 mm Al equivalent, 50 kV potential

Focal spot size: 1 mm

Tube current: 4 mA

Geometry:
- Centre of subject 450 mm from focal spot
- beam size at 450 mm: 8 mm x 8 mm
- width of horizontal sweep: 762 mm
- X-ray beam horizontal sweep: 5 ms
- field moving up 4 mm during each horizontal sweep (5 ms)
- each location (at one sweep) exposed approximately 50 µs
- total scan height: 2 m

Front scan followed by back scan at same conditions

Duration of each scan: 3 s

Dose per screening:
- measured: 6.4 µRem = 0.064 µSv
- calculated/estimated: 5.2 µRem = 0.052 µSv

2. Backscatter scanner:

X-ray spectrum: Tungsten target, 20° anode angle, filtration 1 mm Al equivalent, 50 kV potential

Focal spot size: 1 mm

Tube current: 5 mA

Geometry:
- Centre of inspection area 877 mm from focal spot
- beam size at 877 mm: 5.5 mm x 5.5 mm
- width of horizontal sweep: 1000 mm
- X-ray beam horizontal sweep: 5.45 ms
- field moving up 4.82 mm during each horizontal sweep
- each location (at one sweep) exposed approximately 35 µs
- total scan height: 2.3 m

Front scan followed by back scan at same conditions

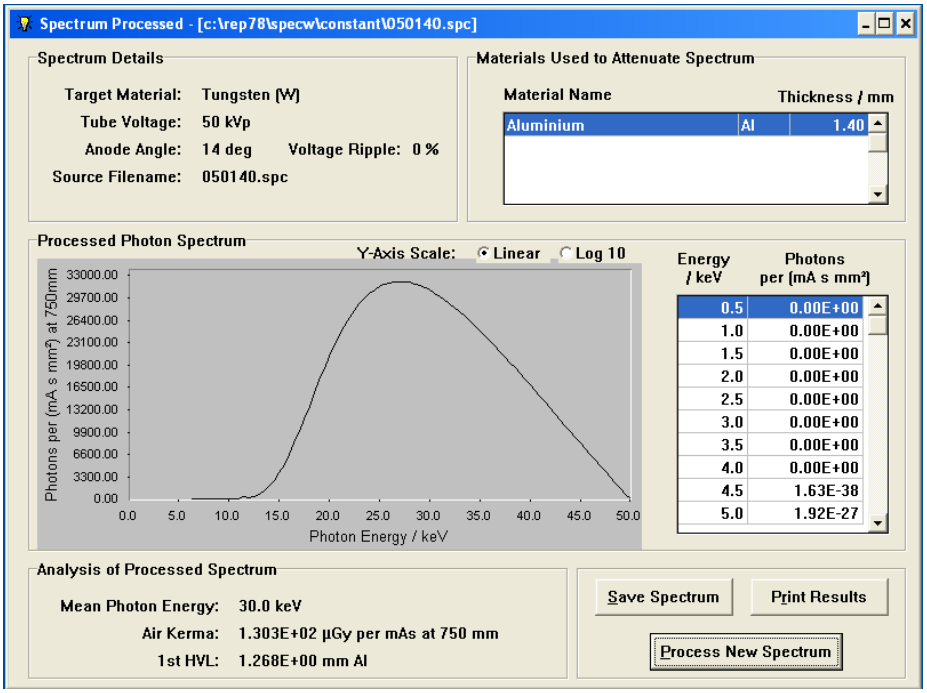
Duration of each scan: 2.6 s

Tilt at top/bottom: ±45° (not exactly specified!)

X-ray spectra

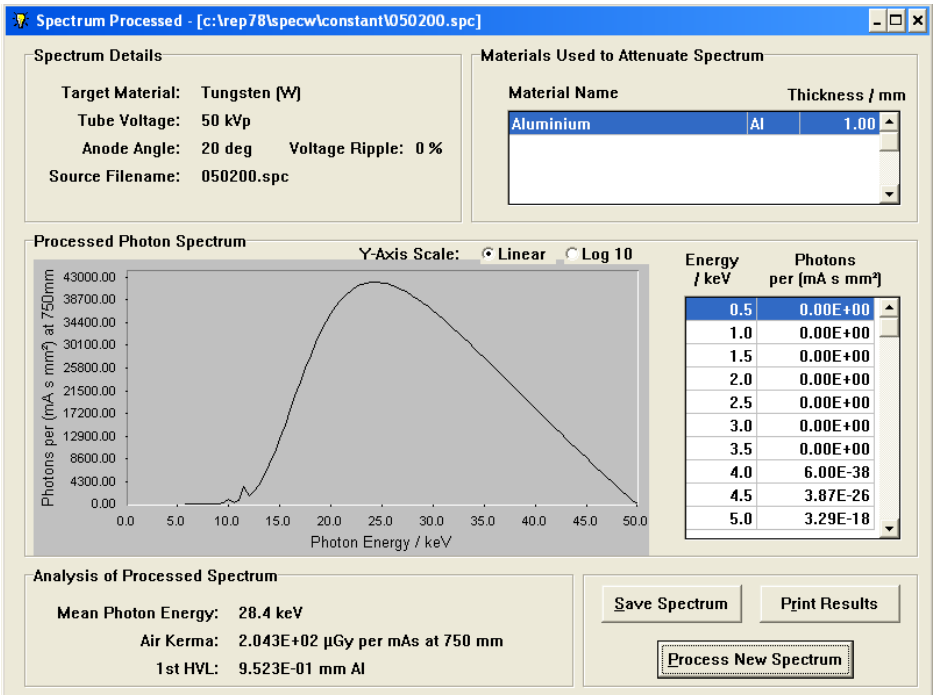
The X-ray spectra were generated using the IPEM spectra generator (Cranley *et al* 1997). They have the following properties:

1. Combined backscatter and transmission scanner:



An air kerma of 130.3 µGy per mAs at 750 mm corresponds to an air kerma of 361.9 µGy per mAs at 450 mm.

2. Backscatter scanner:



An air kerma of 204.3 µGy per mAs at 750 mm corresponds to an air kerma of 149.4 µGy per mAs at 877 mm.

Approximations used in the simulations

The source movement (horizontal and vertical) was not simulated exactly. The following simplifications were introduced in the simulation compared to the real situation:

1. The horizontal sweep was simulated by a fan beam covering the entire field width. The smaller field covered by the flying spot was then accounted for by reducing the exposure time accordingly.
2. The vertical movement was approximated by a sequence of stationary fields where the height difference of the source positions between the single exposures was the height that field would move up during each horizontal sweep.
3. There is a tilt of the X-ray generator relative to the body length axis which was mentioned, but not specified exactly by either manufacturer. This tilt was not simulated at all in the calculations. Since the tilt would increase the distance between the body length axis and the focal spot and hence decrease the air kerma free in air on the body length axis, the horizontal incidence is assumed to result in a conservative estimate of the applied doses.

Monte Carlo calculations performed

The simulations were performed with the renowned Monte Carlo radiation transport code package EGSnrc (Kawrakow *et al.* 2009). The phantoms of the human body used for the calculations were "RCP-AM" and "RCP-AF", the ICRP/ICRU adult male and female reference computational phantoms (ICRP 2009) and "Katja", the phantom of a pregnant woman in the 24th week of gestation (Becker *et al.* 2007, Becker *et al* 2008). The starting energies of the primary photons were sampled from the X-ray spectra described above.

The histories of 500,000 primary photons were followed per source height and incidence direction, resulting in a total of between 352 and 445 million photon histories for a whole-body examination consisting of an AP and a PA scan, depending on the body height and scanner make. The resulting statistical uncertainties (in terms of the coefficients of variance) were well below 1% for most organs and could amount up to 5% for small organs, such as the gall bladder, the thymus and the thyroid. The simulation results per single source simulation were given as organ equivalent doses per air kerma free in air at the reference distance from the focal spot; these conversion coefficients were averaged for all source heights and both directions of incidence, and the multiplied with a value of the air kerma free in air derived as follows:

	Combined backscatter and transmission scanner			Backscatter scanner		
	RCP-AM	RCP-AF	Katja	RCP-AM	RCP-AF	Katja
K_a/mAs at reference distance (µGy/mAs)	361.9	361.9	361.9	149.4	149.4	149.4
Tube current (mA)	4	4	4	5	5	5
Total scan height of device (mm)	1980	1980	1980	2300	2300	2300
Total AP+PA scan time (s)	6	6	6	5.2	5.2	5.2
Scan height for phantom (mm)	1780	1692	1692	1779	1692	1692
AP+PA exposure time (s)	5.39	5.13	5.13	4.02	3.83	3.83
Tube-current-time product (mAs)	21.58	20.51	20.51	20.11	19.13	19.13
K_a at reference distance (µGy)	7808	7422	7422	3004	2858	2858
Flying spot horizontal width (mm)	8.00	8.00	8.00	5.50	5.50	5.50
Field width (mm)	762.00	762.00	762.00	1000.00	1000.00	1000.00
Flying spot field fraction	0.0105	0.0105	0.0105	0.0055	0.0055	0.0055
Effective K_a at reference distance (µGy)	81.98	77.92	77.92	16.52	15.72	15.72

This resulted in the following (organ) equivalent doses:

	Organ equivalent dose (μSv)					
	Combined backscatter and transmission scanner			Backscatter scanner		
	RCP-AM	RCP-AF	Katja	RCP-AM	RCP-AF	Katja
Brain	0.040	0.045	0.039	0.018	0.007	0.007
Gall bladder wall	0.049	0.065	0.089	0.060	0.010	0.010
Stomach wall	0.102	0.124	0.152	0.008	0.022	0.019
Small intestine wall	0.106	0.121	0.052	0.014	0.021	0.010
Heart wall	0.097	0.118	0.167	0.014	0.020	0.020
Liver	0.078	0.115	0.142	0.012	0.020	0.019
Oesophagus	0.071	0.085	0.117	0.038	0.014	0.015
Pancreas	0.054	0.085	0.084	0.009	0.014	0.012
Prostate	0.064			0.010		
Spleen	0.083	0.118	0.052	0.015	0.022	0.022
Thymus	0.176	0.180	0.294	0.031	0.032	0.031
Thyroid	0.248	0.264	0.443	0.045	0.047	0.046
Urinary bladder wall	0.115	0.203	0.177	0.020	0.034	0.017
Uterus	0.104	0.072	0.221	0.017	0.012	0.022
Endosteum	0.054	0.096	0.055	0.011	0.017	0.010
Active bone marrow	0.062	0.077	0.061	0.008	0.013	0.012
Extrathoracic airways (ET)	0.142	0.092	0.144	0.013	0.015	0.015
Adrenals	0.076	0.065	0.038	0.028	0.010	0.010
Breast, total	0.269	0.239	0.410	0.021	0.045	0.045
Colon wall	0.106	0.145	0.084	0.019	0.025	0.013
Eye lenses	0.514	0.390	0.686	0.060	0.071	0.069
Kidneys	0.082	0.096	0.042	0.019	0.017	0.015
Lungs	0.108	0.138	0.128	0.032	0.023	0.024
Lymphatic nodes	0.165	0.172	0.169	0.036	0.031	0.028
Muscle tissue	0.189	0.182	0.148	0.009	0.034	0.033
Ovaries		0.083	0.050		0.013	0.012
Salivary glands	0.108	0.091	0.080	0.025	0.018	0.018
Skin, total	0.398	0.418	0.382	0.089	0.091	0.091
Testes	0.257			0.047		
Foetus total body			0.122			0.012
Effective dose	0.139		(0.160)	0.025		(0.022)

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