



INFORMATION PAPER ON NON-MEDICAL HUMAN IMAGING

Prepared by the Inter-Agency Committee on Radiation Safety (IACRS)¹

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Background and Scope

Non-medical human imaging refers to the intentional exposure of individuals to radiation for purposes other than medical diagnosis, medical treatment or biomedical research. Examples of non-medical human imaging refer to legal purposes, security reasons, health insurance purposes. The IACRS member organizations have received many requests for guidance and clarification related to radiation safety in this matter. For clarification, the IACRS has compiled relevant facts and main requirements applicable to non-medical human imaging presented in this information paper.

Objective

This information paper has been prepared by the IACRS to summarize its common understanding of approaches for the management of exposure due to non-medical human imaging to support the implementation of the safety requirements.

This document is intended for the use of the IACRS member organizations and may also be relevant for governments and other parties responsible for taking decisions concerning the use of such modalities of imaging.

International and European Basic Safety Standards

The IAEA General Safety Requirements Part 3 (GSR Part 3) (also referred to as the International Basic Safety Standards or simply the BSS)[1], as well as the European Council Directive 2013/59/Euratom (also referred to as European BSS)[2] set safety requirements on non-medical human imaging.

The International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, are jointly sponsored by the eight members of the IACRS. The European Basic Safety Standards is legally binding for European Union Member States. Both documents establish requirements or regulations depending on its nature in relation to non-medical imaging.

Additionally, several IAEA Safety Guides provide detailed guidance on justification of practices for the public and workers including non-medical human imaging (GSG-5 [3] and GSG-7 [4] as well as recommendations on specific safety measures to meet the requirements of GSR Part 3 and other relevant Safety Requirements on the use of X ray generators and other types of radiation source that are used for inspection purposes and for non-medical human imaging (SSG-55) [5]. Other IACRS

¹ *The Inter-Agency Committee on Radiation Safety (IACRS) was established in March 1990. Its purpose is to promote consistent policies and to coordinate activities with respect to areas of common interest in radiation protection and safety at the international level (iacrs-rp.org).*

observers, such as the ICRP or IEC have also issued documents relevant to non-medical human imaging [6], [7].

General considerations on the application of radiation protection principles

The introduction of any practice and source of ionizing radiation, requires the legal and regulatory framework for justification, optimization and limitation of exposure. This responsibility lies with the government and/or the regulatory body.

A registrant or licensee of the facility performing the non-medical human imaging procedures is responsible for safe operation of the equipment for which the authorisation was obtained; for justification of exposures of particular individuals; for the optimization of protection and safety; and for the application of dose limits and dose constraints.

Justification

In the case of medical imaging, an exposed individual is subject to the radiation risk but also to the (health) benefits. This is not the case with the non-medical human imaging, when an organization or the society as a whole, rather than an individual, benefits from the exposure, while the (health) risks still remain with the exposed individual.

As a consequence, and as agreed in the International BSS, there are certain human imaging practices deemed to be not justified: those performed as a form of art or for publicity purposes; for occupational, legal or health insurance purposes without reference to clinical indication; for theft detection purposes; and for the detection of concealed objects for purposes.

The government has the responsibility to ensure that radiological and non-radiological detriment considerations are taken into account in the process of justification for any non-medical human imaging practice. Such considerations need to be taken into account because, unlike medical exposures, non-medical human imaging practices do not necessarily yield a direct health benefit to the exposed individual. For such practices, there may be wider benefits to society that should be considered.

If a particular type of practice involving non-medical human imaging is considered to be justified by the government, it has to be subject to regulatory control. The regulatory body, in cooperation with other relevant authorities, agencies and/or professional bodies, has to establish the requirements for regulatory control of the practice and for review of the justification.

For example, the justification of the use of X ray imaging for the detection of concealed objects that could be used for criminal acts that pose a national security threat may be regarded as the first step/stage of justification. Approving the use of such imaging procedures in specific facilities (or types of facility) represents a second step/stage of justification, although often steps/stages one and two may be considered by the government or the regulatory body together. Proposals for application of that practice in other types of facility or situation, such as access control to buildings, should necessitate separate considerations of justification.

The third step/stage of justification relates to the selection of particular individuals to undergo a specific non-medical imaging procedure. Criteria for the selection of individuals should be part of the initial application for justification and should be reviewed by the regulatory body as part of the overall justification process. Particular consideration should be given to the application of non-medical human imaging procedures to children, pregnant women and other sensitive population groups. Further details on the requirements or regulations on justification of non-medical human imaging are provided in Box 1 and 2 as in the International [1] and European BSS [2].

Box 1: Justification of practices (Requirement 10 in the International BSS)

The government or the regulatory body shall ensure that only justified practices are authorized.

3.16. The government or the regulatory body, as appropriate, shall ensure that provision² is made for the justification of any type of practice³ and for review of the justification, as necessary, and shall ensure that only justified practices are authorized.

3.17. The following practices are deemed to be not justified:

- (a) Practices, except for justified practices involving medical exposure⁴, that result in an increase in activity, by the deliberate addition of radioactive substances or by activation⁵, in food, feed, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a person;
- (b) Practices involving the frivolous use of radiation or radioactive substances in commodities or in consumer products such as toys and personal jewellery or adornments, which result in an increase in activity, by the deliberate addition of radioactive substances or by activation⁶;
- (c) Human imaging using radiation that is performed as a form of art or for publicity purposes.

3.18. Human imaging using radiation that is performed for occupational, legal or health insurance purposes⁶, and is undertaken without reference to clinical indication, shall normally be deemed to be not justified. If, in exceptional circumstances, the government or the regulatory body decides that the justification of such human imaging for specific practices is to be considered, the requirements of paras 3.61–3.64 and 3.66 shall apply.

3.19. Human imaging using radiation for theft detection purposes shall be deemed to be not justified.

3.20. Human imaging using radiation for the detection of concealed objects for anti-smuggling purposes shall normally be deemed to be not justified. If, in exceptional circumstances, the government or the regulatory body decides that the justification of such human imaging is to be considered, the requirements of paras 3.61–3.67 shall apply.

3.21. Human imaging using radiation for the detection of concealed objects that can be used for criminal acts that pose a national security threat shall be justified only by the government. If the government decides that the justification of such human imaging is to be considered, the requirements of paras 3.61–3.67 shall apply.

² Such provision may involve several governmental authorities not necessarily having direct responsibility for protection and safety, such as ministries of health, justice, immigration, and security.

³ This provision for the justification of any type of practice includes practices for which notification alone is sufficient.

⁴ Particular requirements for the justification of medical exposure are specified in paras 3.155–3.161.

⁵ This requirement is not intended to prohibit those practices that may involve the short-term activation of commodities or products, for which there is no increase in radioactivity in the commodity or product as made available.

⁶ Such purposes for performing human imaging using radiation include: assessment of fitness for employment (prior to employment or periodically during employment); assessment of physiological suitability for a career or a sport; assessment of athletes before a selection or transfer; determination of age for legal purposes; obtaining evidence for legal purposes; detection of drugs concealed within the body; immigration or emigration requirements; pre-insurance checks; and obtaining evidence for the purposes of a compensation claim.

Box 2**Non-medical imaging in Council Directive 2013/59/Euratom
(the European Basic Safety Standards)**

European Union Member States are bound to comply with the obligations laid down in the legally binding Council Directive 2013/59/Euratom. In this Directive, non-medical imaging exposure means “any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed.” On practices involving non-medical imaging purposes, the requirements can be summarised as follows:

- EU Member States shall ensure the identification of practices involving non-medical imaging exposure (an indicative list of practices is provided in annex to the Directive).
- EU Member States shall also ensure that all types and each application of a generally accepted type of practice involving non-medical imaging exposure are justified. Moreover, all individual non-medical imaging exposure procedures using medical radiological equipment shall be justified in advance, taking into account the specific objectives of the procedure and the characteristics of the individual involved. Justification may be subject to review and circumstances warranting non-medical imaging exposures without individual justification of each exposure shall be subject to regular review.
- EU Member States may exempt justified practices involving non-medical imaging exposure using medical radiological equipment from the requirement for dose constraints and dose limits specified for public exposure.
- When a particular practice is justified, it shall be subject to authorisation. Requirements for the practice, including criteria for individual implementation, are established by the competent authority, in cooperation with other relevant bodies and medical scientific societies, as appropriate.
- For procedures using medical radiological equipment, relevant requirements identified for medical exposure are applied, including for equipment, optimization, responsibilities, training and special protection during pregnancy and the appropriate involvement of the medical physics expert. Specific protocols and diagnostic reference levels are put in place when practicable.
- For procedures not using medical radiological equipment, dose constraints are significantly below the dose limit for members of the public.
- Information is provided to and consent sought from the individual to be exposed, allowing for cases where the law enforcement authorities may proceed without consent of the individual according to national legislation.

Dose limitation

Dose limitation applies to individuals in different ways:

- i. Individuals whose work is to ensure the performance of the imaging equipment, including maintenance, calibration, surveillance, and other activities that are necessary for proper control and operation of the source, are considered occupationally exposed. Requirements on occupational protection and dose limitation apply to these individuals. Whether the operators of equipment are considered occupationally exposed personnel will depend on the national regulatory requirements, the type and mode of operation of the equipment.

- ii. Exposure of other individuals who are not being screened but may be in the vicinity of the screening activity should be considered as public exposure.
- iii. For some people including frequent air travellers, couriers, and drivers of cargo vehicles, it is possible that they may be screened multiple times per day, week, or month. Furthermore, there are other groups of individuals who may, as part of their duties, be screened with some significant frequency. For example, various ground personnel in airports who may enter and exit the security area multiple times per day, flight crews, etc. Even though their entry into secure areas subject to screening is required as part of the job requirements, they do not fall in the category of occupationally exposed workers. Their exposures are not directly related to their occupational duties, and screened individuals may, or may not, be employed by the operating management of the screening equipment. Such exposures should be considered as public exposure.
- iv. All individuals that undergo non-medical imaging procedures are considered members of the public, and so should be provided protection consistent with that provided for a member of the public, including application of the respective dose limits.

The registrant or licensee is required to develop, document and implement a radiation protection and safety programme that covers the main elements contributing to protection and safety. The structure and contents of the radiation protection and safety programme should be documented to an appropriate level of detail. In particular, operators' training and quality control of the equipment is of paramount importance.

Optimization

Exposures resulting from non-medical human imaging must be optimized. Dose constraints for occupational and public exposure need to be in place.

Optimization requirements for the non-medical human imaging exposure of the public should be applied using dose constraints which, in the case where the non-medical human imaging is performed by medical personnel, should be established in consultation with relevant authorities, professional bodies and the regulatory body. The dose constraints may be based on the use of specific values, similar to diagnostic reference levels (DRLs), applied in medical exposures. However, even if the parts of the human body exposed for medical diagnostics are the same as for the non-medical imaging, since the purpose of exposure is different, the quality of the image required is different, and thus, direct application of the DRL values is not always possible. For non-medical human imaging performed by medical personnel, other requirements generally identified for medical exposures are also applicable, including those for equipment, optimization, responsibilities, training, involvement of a medical physics expert and specific protocols.

In the case of non-medical human imaging involving inspection imaging devices that are operated by non-medical personnel and which produces images that are viewed by persons who are usually not radiological medical practitioners, the dose constraints that apply to individuals should be significantly below the dose limits for public exposure.

Constraints in terms of the number of individuals scanned and the number of scans per individual in a given year should be considered. In practice, the use of systems should be applied with discretion in terms of the selection of individuals to be scanned and the number of scans per individual per year. The individual doses for some members of the public could be of concern when multiple scans are done and health effects could become of concern.

Dose constraints for occupational exposure of individuals operating security screening systems should normally be set at a fraction of the dose limit for occupational exposure. Well-designed and maintained systems, including adequate shielding and the provision of adequate distance from the source are essential to ensure the areas where operators are present have no or very low level of radiation. For mobile settings, it is very important to establish the appropriate arrangements and control of areas to avoid unnecessary exposures of individuals working with the mobile system. An appropriate QA programme is important to ensure correct functioning of the equipment and use of procedures by the operators.

It is natural that people have concerns because of the involuntary nature of exposures, and the uncertain nature of any possible consequences. In such circumstances, individuals tend to desire a greater degree of protection than when exposure is undertaken voluntarily, or the individual has some degree of control.

Health considerations

From a health perspective, the radiation risks of non-medical human imaging can be assessed, though with uncertainties, by applying the linear non-threshold risk model extrapolated from epidemiology data. In contrast, although in some cases the benefit for the community may be underpinned by a strong legal, security or safety reason with public health implications, the assessment of the benefits of non-medical human imaging is often subjective and requires an ethical decision-making process to be embedded in the justification of such practices.

Individual doses in non-medical imaging largely depend on the type of procedure and imaging device, but usually they are very low, as well as their associated radiation risks. However, in certain scenarios individuals may be repeatedly exposed, (e.g. workers frequently screened because of occupational duties, frequent air travellers undergoing airport security screening), and potentially accumulate higher doses.

Ethical considerations

Ethical principles regarding consent, confidentiality, privacy, non-discrimination and dignity – among others - require particular consideration for people undergoing non-medical human imaging and need to be included in the decision-making process.

Provision of information to and request of consent from the individuals subject to non-medical imaging procedure is mandatory as well as availability of alternative procedures. In either case considerations with regards to ethics is needed, as it might be very discomforting for individuals to appear as an image or to be searched manually in public. Also, individuals suspected of criminal action and subjected to imaging procedures may suffer from embarrassment and shame.

References for further reading:

1. EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).
2. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom
3. INTERNATIONAL ATOMIC ENERGY AGENCY, Justification of Practices, Including Non-medical Human Imaging, IAEA Safety Standards Series No. GSG-5, IAEA, Vienna (2014).
4. INTERNATIONAL ATOMIC ENERGY AGENCY, Occupational radiation protection, IAEA Safety Standards Series No. GSG-7, IAEA, Vienna (2018).
5. INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation safety of X-ray generators and other radiation sources used for inspection purposes and for non-medical human imaging, IAEA Safety Standards Series No SSG-55, (2020).
6. INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Security Screening, ICRP Publication 125, SAGE (2014).
7. IEC 62463 (2010) Radiation protection instrumentation – X-ray Systems for the screening of persons for security and the carrying of illicit items.

Annex:
Types of non-medical human imaging practices

The various types of non-medical human imaging can be grouped into two categories based on their common attributes, as 'Category 1' and 'Category 2':

Category 1 non-medical human imaging: is performed by medical personnel, typically radiology personnel; produces images that are assessed by a radiological medical practitioner; usually takes place in a medical facility that performs radiological medical procedures; uses medical radiological equipment to obtain the images. Category 1 non-medical human imaging includes:

- Imaging for occupational and employment related purposes, such as assessment of fitness for employment (prior to employment or periodically during employment), and assessment of physiological suitability for a career or a sport, including assessment of athletes before a selection or transfer;
- Imaging for legal purposes, including obtaining legal evidence, age determination, immigration or emigration purposes not related to health screening programmes, and detection of drugs within a person;
- Imaging for health insurance purposes, including pre-insurance checks and obtaining evidence for the purposes of a compensation claim.

Category 2 non-medical human imaging involves inspection imaging devices that are operated by non-medical personnel and produces images that are viewed by persons who are usually not radiological medical practitioners. This practice takes place in a non-medical facility, such as an airport, seaport, railway station, cross-border station or access to a secure facility, where imaging is used to detect concealed objects for anti-smuggling purposes and for the detection of concealed objects that could be used for criminal acts that pose a security threat. A Category 2 non-medical human imaging procedure may involve more than one scan and produce more than one image.

Imaging devices can also be categorized in terms of how they could be deployed. There are two categories of use, often referred to as 'general use' and 'limited use', which are defined as follows:

- (a) **General use systems** are characterized by delivering a very low dose per exposure to the person undergoing the imaging procedure, typically an effective dose ranging between 0.003 and 0.1 μSv per scan, depending on the equipment and corresponding shielding applied. The basis for this categorization is that such systems can, in principle, be used with little concern about the number of individuals scanned and the number of scans per individual in a given year.
- (b) **Limited use systems** are characterized by delivering a higher dose per exposure to the person undergoing the imaging procedure, typically greater than 0.1 μSv effective dose per scan, and up to 10 μSv per scan. This level of exposure, although low, may raise issues from the perspectives of cumulative individual dose and collective dose.