IAEA Safety Standards

for protecting people and the environment

Radiation Safety of X Ray Generators and Other Radiation Sources Used for Inspection Purposes and for Non-medical Human Imaging

Specific Safety Guide

No. SSG-55

IAEA
International Atomic Energy Agency

IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety. The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

Information on the IAEA's safety standards programme is available on the IAEA Internet site

https://www.iaea.org/resources/safety-standards

The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at: Vienna International Centre, PO Box 100, 1400 Vienna, Austria.

All users of IAEA safety standards are invited to inform the IAEA of experience in their use (e.g. as a basis for national regulations, for safety reviews and for training courses) for the purpose of ensuring that they continue to meet users' needs. Information may be provided via the IAEA Internet site or by post, as above, or by email to Official.Mail@iaea.org.

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Reports on safety in nuclear activities are issued as **Safety Reports**, which provide practical examples and detailed methods that can be used in support of the safety standards.

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Security related publications are issued in the **IAEA Nuclear Security Series**.

The **IAEA Nuclear Energy Series** comprises informational publications to encourage and assist research on, and the development and practical application of, nuclear energy for peaceful purposes. It includes reports and guides on the status of and advances in technology, and on experience, good practices and practical examples in the areas of nuclear power, the nuclear fuel cycle, radioactive waste management and decommissioning.

RADIATION SAFETY OF X RAY GENERATORS AND OTHER RADIATION SOURCES USED FOR INSPECTION PURPOSES AND FOR NON-MEDICAL HUMAN IMAGING

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

IAEA SAFETY STANDARDS SERIES No. SSG-55

RADIATION SAFETY OF X RAY GENERATORS AND OTHER RADIATION SOURCES USED FOR INSPECTION PURPOSES AND FOR NON-MEDICAL HUMAN IMAGING

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FOREWORD

The IAEA's Statute authorizes the Agency to "establish or adopt… standards of safety for protection of health and minimization of danger to life and property" — standards that the IAEA must use in its own operations, and which States can apply by means of their regulatory provisions for nuclear and radiation safety. The IAEA does this in consultation with the competent organs of the United Nations and with the specialized agencies concerned. A comprehensive set of high quality standards under regular review is a key element of a stable and sustainable global safety regime, as is the IAEA's assistance in their application.

The IAEA commenced its safety standards programme in 1958. The emphasis placed on quality, fitness for purpose and continuous improvement has led to the widespread use of the IAEA standards throughout the world. The Safety Standards Series now includes unified Fundamental Safety Principles, which represent an international consensus on what must constitute a high level of protection and safety. With the strong support of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its standards.

Standards are only effective if they are properly applied in practice. The IAEA's safety services encompass design, siting and engineering safety, operational safety, radiation safety, safe transport of radioactive material and safe management of radioactive waste, as well as governmental organization, regulatory matters and safety culture in organizations. These safety services assist Member States in the application of the standards and enable valuable experience and insights to be shared.

Regulating safety is a national responsibility, and many States have decided to adopt the IAEA's standards for use in their national regulations. For parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by regulatory bodies and operators around the world to enhance safety in nuclear power generation and in nuclear applications in medicine, industry, agriculture and research.

Safety is not an end in itself but a prerequisite for the purpose of the protection of people in all States and of the environment — now and in the future. The risks associated with ionizing radiation must be assessed and controlled without unduly limiting the contribution of nuclear energy to equitable and sustainable development. Governments, regulatory bodies and operators everywhere must ensure that nuclear material and radiation sources are used beneficially, safely and ethically. The IAEA safety standards are designed to facilitate this, and I encourage all Member States to make use of them.

THE IAEA SAFETY STANDARDS

BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care, and are expected to fulfil their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property, and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation, and to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and security measures[1] have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1).

Safety Fundamentals

Safety Fundamentals present the fundamental safety objective and principles of protection and safety, and provide the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. Requirements, including numbered ‘overarching’ requirements, are expressed as ‘shall’ statements. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it

[1] See also publications issued in the IAEA Nuclear Security Series.

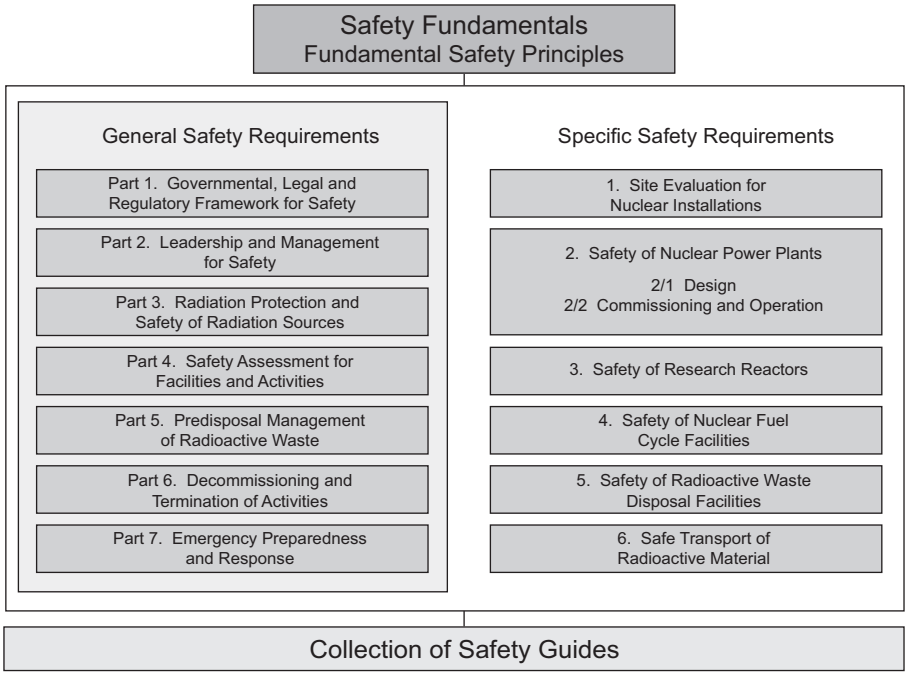

FIG. 1. The long term structure of the IAEA Safety Standards Series.

is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as 'should' statements.

APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be

used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including the development of educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to be assessed at the national level. For example, many of the IAEA safety standards, in particular those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and five safety standards committees, for emergency preparedness and response (EPReSC) (as of 2016), nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the Commission on Safety Standards is appointed by the Director General and includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards.

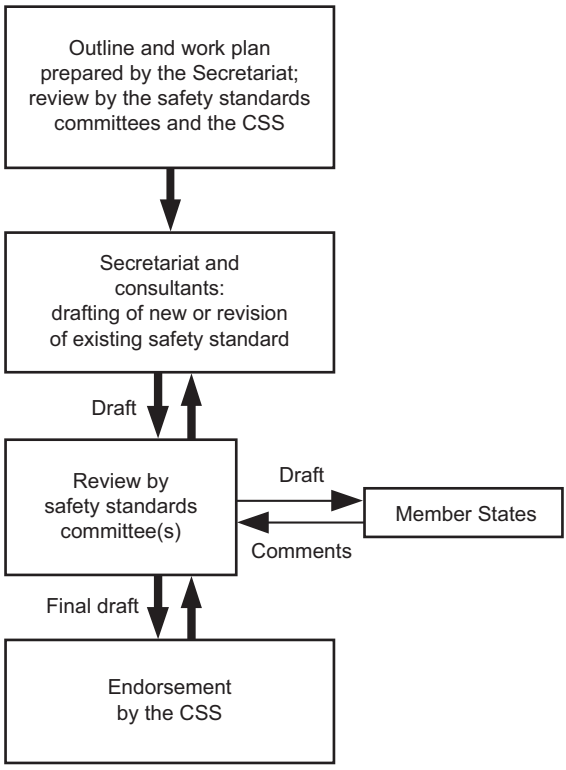

FIG. 2. The process for developing a new safety standard or revising an existing standard.

It articulates the mandate of the IAEA, the vision for the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

INTERPRETATION OF THE TEXT

Safety related terms are to be understood as defined in the IAEA Safety Glossary (see http://www-ns.iaea.org/standards/safety-glossary.htm). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard in the IAEA Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text, and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. Annexes and footnotes are not integral parts of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material under other authorship may be presented in annexes to the safety standards. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [1], specifies the basic requirements for protection of people against exposure to radiation and for the safety of radiation sources. The application of these requirements helps to ensure that the number of people exposed to radiation and their doses are kept as low as reasonably achievable, and helps to prevent accidents involving radiation sources and to mitigate the consequences of accidents should they occur. This Safety Guide provides guidance for implementing the requirements in GSR Part 3 [1] with regard to the safe use of X ray generators and other types of radiation source that are used for inspection purposes and for imaging of humans for purposes other than medical diagnosis, medical treatment or biomedical research (see also the International Commission on Radiological Protection report, Radiological Protection in Security Screening [2]).

1.2. The deliberate exposure of humans to ionizing radiation is usually in the context of medical diagnosis or treatment of patients, or for the purpose of biomedical research. In these cases, the benefits to the patient from the radiation exposure (or in the case of biomedical research, the benefit to health care and society in general) are expected to outweigh any radiation detriment to the people exposed. The system of radiation protection for those situations in which humans are deliberately exposed is well established, for example in GSR Part 3 [1] and IAEA Safety Standards Series No. SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiation [3].

1.3. There are other situations in which people might be deliberately exposed, typically in order to produce an image, but not for medical purposes. In accordance with Requirement 10 of GSR Part 3 [1], certain non-medical applications of human imaging are automatically deemed to be not justified. In other cases, the use of human imaging may be considered to be justified following a formal justification process as described in para. 3.61 of GSR Part 3 [1]. The purpose of these practices might be for many reasons, including security, law enforcement, legal proceedings, insurance concerns and immigration requirements. Events in global and national security, together with the development of sophisticated security imaging technologies, have heightened interest in security activities with the potential for further increases in the use of non-medical human imaging techniques.

1.4. The various types of human imaging for purposes other than medical diagnosis, medical treatment or biomedical research can be grouped into two categories based on their common attributes, referred to in this Safety Guide and IAEA Safety Standards Series No. GSG-5, Justification of Practices, Including Non-medical Human Imaging [4], as 'Category 1' and 'Category 2'[1]:

(a) Category 1 non-medical human imaging: usually takes place in a medical radiation facility that performs radiological procedures for the primary purpose of medical diagnosis; uses medical radiological equipment to obtain the image; is performed by medical personnel, typically radiology personnel; and produces images that are assessed by a radiological medical practitioner. 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, 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.

(b) Category 2 non-medical human imaging involves inspection imaging devices that are operated by personnel who are not specialists in radiology, and produces images that are viewed by persons who are usually not medically qualified. This practice takes place in a non-medical facility, such as an airport, seaport, railway station or cross-border station, 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.

1.5. Some types of human imaging can occur in both categories. Human imaging for the purpose of detecting concealed drugs might be undertaken using medical radiology equipment in a medical radiation facility for legal purposes (i.e. Category 1 human imaging), or with an inspection imaging device in a non-medical facility, for example offices of the customs authority at an airport (i.e. Category 2 human imaging).

[1] The use of Category 1 and Category 2 for the two categories of non-medical human imaging is different from the categorization of sealed radioactive sources in Schedule II of GSR Part 3 [1] ('Categories 1–5').

1.6. Irrespective of whether the practice is Category 1 or 2, Requirement 18 of GSR Part 3 [1] applies:

> "**The government shall ensure that the use of ionizing radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research is subject to the system of protection and safety.**"

1.7. In addition to the non-medical human imaging practices described above, there has been a large increase in the use of inspection imaging devices to detect concealed objects in postal items, baggage and cargo, or within vehicles. Workers and members of the public might be exposed to radiation during the use of such equipment. In addition to exposure of workers operating inspection imaging devices, the use of such devices might lead to the inadvertent exposure of people inside cargo containers, or the exposure of drivers and passengers inside vehicles being inspected.

1.8. This Safety Guide is part of a series of Safety Guides that have been published, or are in preparation, for facilities and activities that cover the use of radioactive sources and X ray generators in industrial uses of ionizing radiation, for example industrial irradiators, industrial radiography, radioisotope production facilities, nuclear gauges, well logging and the use of radiation sources in research and education [5–9].

1.9. It is assumed in this Safety Guide that the State has in place an effective governmental, legal and regulatory infrastructure for radiation protection and safety that covers the use of X ray generators and other types of radiation source that are used for inspection purposes and for non-medical human imaging.

OBJECTIVE

1.10. The objective of this Safety Guide is to provide recommendations on specific safety measures to meet the requirements of GSR Part 3 [1] and other relevant Safety Requirements publications 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.

1.11. The recommendations in this Safety Guide are primarily for organizations that are authorized to use X ray generators and other types of radiation source for inspection purposes and for non-medical human imaging, as well as for radiation

protection experts, radiation protection officers and staff of regulatory bodies. This may also be of interest to designers and manufacturers of X ray generators and other types of radiation source that are used for inspection purposes and for non-medical human imaging.

SCOPE

1.12. This Safety Guide provides recommendations and guidance on protection and safety for X ray generators and other types of radiation source that are used for inspection purposes and for non-medical human imaging. The use of such sources is a planned exposure situation, as defined in GSR Part 3 [1].

1.13. This Safety Guide considers the occupational exposure of workers who operate X ray generators and other types of radiation source that are used for inspection purposes and for non-medical human imaging. This Safety Guide also considers public exposure from the operation of equipment for inspection purposes, and exposure of persons while undergoing non-medical human imaging procedures.

1.14. The phrase used in GSR Part 3 [1] is "**human imaging for purposes other than medical diagnosis, medical treatment or biomedical research**". In this Safety Guide, 'non-medical human imaging' is used as an equivalent phrase. Similarly, the terms 'Category 1 non-medical human imaging' and 'Category 2 non-medical human imaging' are used to refer to the respective categories of human imaging for purposes other than medical diagnosis, medical treatment or biomedical research described in para. 1.4.

1.15. In this Safety Guide, the term 'Category 2 non-medical human imaging facility' means the room or area in which the inspection imaging device or devices are located and operated. A Category 2 non-medical human imaging facility is usually part of a much larger facility, such as an airport. In this Safety Guide, all other areas of the wider facility are considered to be in the public domain, and outside the scope of this Safety Guide.

1.16. GSR Part 3 [1] defines an 'inspection imaging device' as an "imaging device designed specifically for imaging persons or cargo conveyances for the purpose of detecting concealed objects on or within the human body or within cargo or a vehicle." The images produced by such devices can be a single picture, or can be real-time video.

1.17. In this Safety Guide, the general term ‘inspection device’ is used to describe all devices that are used for inspection purposes, including those devices within the GSR Part 3 [1] definition of ‘inspection imaging device’, and the term also includes devices that use a radiation source as part of a process to detect residues on the human body, or to identify or detect material or residues on or within objects such as bottles, baggage, cargo and vehicles. Additional information on specific types of device and specific purposes of inspection is included, as appropriate.

1.18. This Safety Guide provides information on the need for appropriate nuclear security measures and on their interface with safety measures, but does not provide specific guidance on such nuclear security aspects. Additional security guidance can be found in the IAEA Nuclear Security Series.

1.19. This Safety Guide does not cover medical exposures.

STRUCTURE

1.20. Section 2 of this Safety Guide provides recommendations on the use of X ray generators and other radiation sources for the purpose of inspecting objects such as baggage, cargo and vehicles. It includes: a description of the types of inspection device considered in this Safety Guide; the framework for protection and safety for the use of inspection devices; the application of the radiation protection principles of justification, optimization of protection and safety, and dose limits; the elements of a radiation protection programme covering the use of inspection device arrangements for the protection of workers and the public; the safety of facilities where inspection devices are used; the safety aspects of the design of inspection devices; quality assurance programmes; the management of disused radioactive sources; the transport of mobile inspection devices that contain radioactive sources; the investigation of events; and the arrangements for emergency preparedness and response.

1.21. Section 3 provides recommendations on the use of inspection imaging devices and of medical radiological equipment for non-medical human imaging. It includes: a description of the types of inspection imaging device used; the framework for protection and safety for non-medical human imaging; the application of the radiation protection principles of justification, optimization of protection and safety and dose limits; the elements of a radiation protection programme; the protection of workers carrying out non-medical human imaging procedures; the protection of persons undergoing non-medical human imaging

procedures; the protection of the public; safety aspects for non-medical human imaging inspection devices, such as the design of the devices, the design of the facilities housing the devices; the quality assurance programmes for such devices; and the investigation of incidents.

1.22. The Appendix to this Safety Guide sets out the dose limits for workers and for the public, reproduced from Schedule III of GSR Part 3 [1].

2. THE USE OF X RAY GENERATORS AND RADIATION SOURCES FOR INSPECTION PURPOSES

TYPES OF RADIATION SOURCE USED IN INSPECTION DEVICES

X ray generators

2.1. X rays used in inspection imaging devices are either generated by an X ray vacuum tube or by a linear accelerator. X rays generated by this type of equipment have a broader energy spectrum than gamma rays emitted by the radioactive sources described in para. 2.5. The power source for X ray systems is electrical, usually provided by the main electricity supply or, for mobile equipment, by an electrical generator or by batteries.

2.2. X ray tubes typically have a maximum operating voltage of 450 kVp, which limits the penetrating power to less than 100 mm of steel. X ray tube technology is used for inspecting a variety of objects, including letters, parcels, baggage, air cargo containers and vehicles.

2.3. Linear accelerators are normally used for the inspection of cargo containers. They can have an energy output of up to 9 MeV, with the ability to penetrate more than 400 mm of steel. At energies below 2 MeV, the X ray penetration is not sufficient for heavily loaded containers. Many manufacturers of cargo inspection devices have found that linear accelerators operating between 3 MeV and 6 MeV offer the best balance between overall performance and cost. A 3 MeV mobile unit can penetrate more than 220 mm of steel, and a 6 MeV relocatable unit up to 350 mm of steel. A linear accelerator operating at 9 MeV or higher can generate activation products by photoneutron capture reactions, and safety measures may be needed to avoid exposure to elevated dose rates [10]. For energies significantly

above 9 MeV, neutron production is an unwanted by-product and extensive shielding is required.

2.4. Inspection imaging devices can use either a backscatter system or a transmission system to create an image. A backscatter system makes use of the radiation scattered or deflected from an object (or person, as is considered in Section 3) to form an image of the surface (or near surface) of the object (or person). In comparison, a transmission system uses conventional means of radiographic imaging in which the X rays pass through an object (or person) and create an image that includes any internal objects, such as contraband.

Gamma sources

2.5. Gamma rays produced by the decay of radionuclides such as ^{137}Cs and ^{60}Co have been used in inspection devices, although devices using X ray tubes or linear accelerators are gaining preference in some countries. An inspection imaging device using a ^{60}Co source can penetrate up to 150 mm of steel; the typical activity of a ^{60}Co source for this kind of application is around 50–100 GBq, although activities up to 10 TBq have been used. Inspection imaging devices containing radioactive sources give rise to specific safety concerns, as the source continually emits radiation and presents a potential risk of exposure over the course of its useful life. Appropriate disposal of the source at the end of its useful life has to be arranged.

Beta sources

2.6. Electron capture devices used for the detection of trace quantities of explosives and narcotics use a ^{63}Ni radioactive source, which emits beta particles with a maximum energy of 67 keV. In such an inspection device, the typical activity of the ^{63}Ni source is 555 MBq.

Neutron sources

2.7. Neutron sources are used for producing an image or identifying specific materials in cargo through neutron activation analysis. When neutrons collide with the atoms of a given material, characteristic gamma rays are emitted. These gamma rays provide information that allows certain constituent chemical elements to be detected and identified, particularly those present in materials such as drugs, explosives and chemical weapons. Techniques such as thermal neutron activation, fast neutron activation, pulsed fast neutron activation and associated particle imaging have been developed for security operations [11].

2.8. Neutron scanning is often considered as a tool for providing additional information when used in conjunction with X ray or gamma radiation scanning.

2.9. Fast neutron sources and thermal neutron sources may be used. Neutron generators based on a deuterium–deuterium reaction, which produces 2.5 MeV neutrons, or a deuterium–tritium reaction, which produces 14.1 MeV neutrons, have been developed. Radionuclides such as ^{252}Cf have also been used in some applications.

2.10. Some neutron sources require substantial shielding, and raise the same safety issues as the sources referred to in para. 2.5.

TYPES OF INSPECTION DEVICE

Post room scanners and baggage inspection systems

2.11. Post room scanners for inspecting mail, small parcels and small bags normally utilize X ray equipment operating at up to 80 kVp. Baggage inspection units usually use X ray equipment operating in the range of 80–160 kVp. Baggage inspection systems are usually fixed systems at the entrance to public buildings, including airports. These inspection devices incorporate interlocks and other safety features to prevent internal access to the area where radiation is produced.

Inspection devices to detect explosives and narcotics in bottles containing liquids

2.12. X ray inspection devices are used for the analysis and screening of the contents of containers of liquids or gels (e.g. bottles of alcohol, water, perfumes, tubes of cosmetic gels) up to a volume of approximately 2 litres to detect explosives or narcotics. The screening usually takes place at security check points, such as at border crossings, and the devices are operated by customs or border security personnel.

2.13. These devices typically use 160 kVp X rays. The X rays should be capable of being switched on only when all panels and safety interlocks are in a safe position and the X ray enable key switch is in the on position.

Hand-held backscatter inspection imaging devices

2.14. Hand-held backscatter inspection imaging devices are used for security and other inspection purposes. Hand-held backscatter devices produce a low energy, low dose rate X ray beam used for the detection of organic threats, contraband and explosives. These devices are usually operated with an X ray tube voltage of 70 kVp. They are particularly useful for the detection of low atomic number elements associated with explosives and narcotics. The unit produces an image of the scanned object from the backscattered X rays. The units are used by customs, border enforcement and security officials. Since the units are hand-held and produce an open beam, there is a controlled area of around 3 m in front of the device. The boundary of the controlled area should be set to ensure that possible doses to people outside the controlled area are below the relevant dose constraint.

Portable X ray radiography inspection imaging devices

2.15. Portable X ray units are used for on-site examination of suspicious objects for security purposes. The units consist of a portable X ray generator and an imaging system that is placed behind the object to be inspected. The X ray generators are operated in a pulse mode and can generate X rays up to 250–300 kVp. The device produces an open X ray beam and a controlled area needs to be established around the object being examined. The boundary of the controlled area should be set to ensure that possible doses to people outside the controlled area are below the relevant dose constraint.

Inspection devices for trace quantities of explosives and narcotics

2.16. Inspection devices that are used to detect trace quantities of explosives and narcotics are based on swab or air sampling of particulate and vapour on persons and their belongings. The screening usually takes place at security check points, such as those at airports and ports, by customs or border security personnel. Inspection devices based on an electron capture detector system incorporate one or more ^{63}Ni sources, as described in para. 2.6.

Inspection imaging devices for scanning vehicles

2.17. Vehicle scanners use X ray generators typically operating above 160 kVp. The energy requirements of the inspection unit are determined by the size and composition of the object to be inspected. The vehicle is driven through the scanner, around which a controlled area has been established. The boundary

of the controlled area should be set to ensure that doses to people outside the controlled area are below the relevant dose constraint.

Inspection imaging devices for scanning cargo

2.18. Fixed cargo scanning devices utilize the most powerful radiation beams, typically with a photon energy of up to 9 MeV. As recommended in Ref. [12], the device should be housed in a purpose built facility with walls of sufficient thickness to provide adequate shielding. The facility will normally also include interlocked doors at entrances to the screening area [12].

2.19. Relocatable scanning devices typically operate at 6 MeV, and need lighter infrastructure and less shielding than fixed devices. As noted in Ref. [12], some relocatable scanning devices can be operated in the open without needing additional shielding. However, all relocatable cargo scanning devices involve the designation of a controlled area during operation, from which all employees and members of the public are excluded during the scanning of conveyances [13]. The boundary to the controlled area depends on the beam output, size and direction, as well as on the amount of shielding provided.

2.20. Mobile scanning devices typically operate at 3–6 MeV (gamma sources are sometimes used). Mobile devices usually comprise a scanner system built onto a vehicle chassis, or they can be constructed as articulated units that can be towed. Mobile scanning devices require a controlled area during operation that should be determined on a case by case basis. The boundary to the controlled area depends on the beam output, size and direction.

2.21. Systems in which the cargo being scanned is moving (‘drive through systems’) operate at beam energies typically in the range of 3–6 MeV. Such systems enable a much higher throughput; however, drivers normally remain in the cabin of the vehicle while a container is scanned. Consequently, such systems include safety features to ensure that the driver is not exposed to the main beam or to unacceptable levels of scattered radiation. Such systems can operate in the open, although, as recommended in Ref. [12], the effects of wind, snow, sand and rain should be considered. Drive through systems include train scanning systems, which are most commonly used at border crossings.

Responsibilities of the government

2.22. The roles and responsibilities of the government[2] with regard to protection and safety are set out in Requirement 2 and paras 2.13–2.28 of GSR Part 3 [1], with further detailed requirements given in IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [14]. These include the following:

(a) Establishing an effective legal and regulatory framework for protection and safety for all exposure situations.
(b) Establishing legislation that meets specified requirements.
(c) Establishing an independent regulatory body with the necessary legal authority, competence and resources.
(d) Establishing requirements for education and training in protection and safety.
(e) Ensuring that arrangements are in place for the provision of:
    (i) Technical services in relation to protection and safety, such as services for personal dosimetry, environmental monitoring, and the calibration of monitoring and measuring equipment;
    (ii) Education and training services.

All of these are relevant to the safe use of ionizing radiation in inspection devices.

Responsibilities of the government or regulatory body

2.23. Paragraph 3.16 of GSR Part 3 [1] (footnote omitted) states:

> "The government or the regulatory body, as appropriate, shall ensure that provision is made for the justification of any type of practice…and shall ensure that only justified practices are authorized."

2.24. GSG-5 [4] provides recommendations to governments and regulatory bodies on the approach that should be adopted in considering whether the introduction of a particular type of practice in a planned exposure situation is justified.

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[2] States have different legal structures and therefore the term 'government', as used in the IAEA safety standards, is to be understood in a broad sense, and is accordingly interchangeable here with the term 'State'.

2.25. In accordance with para. 3.120 of GSR Part 3 [1], the government or the regulatory body is required to establish or approve dose constraints for public exposure in respect of a source within a practice, to ensure that the total dose to members of the public is not expected to exceed the dose limit as a result of exposure arising from planned operation of all sources under control. One approach that can be taken is to set a dose constraint for public exposure arising from a single facility at some fraction of the dose limit. Some States use a dose constraint of approximately one third or one quarter of the dose limit for public exposure. In establishing or approving such a value, the government or regulatory body should consider the number and type of radiation sources in use in a particular State or region to which the public might be exposed. Further guidance on establishing dose constraints is given in IAEA Safety Standards Series No. GSG-8, Radiation Protection of the Public and the Environment [15].

2.26. The dose constraints established for public exposure should also apply to those persons who might be exposed to radiation while inside a cargo container or vehicle. The exposure of persons in this way should be considered to be public exposure in a planned exposure situation, and hence subject to the dose constraints and dose limits for public exposure.

Responsibilities of the regulatory body

2.27. The functions of the regulatory body, such as establishing regulations and guides, authorizing and inspecting facilities and activities, and enforcing regulatory requirements, are described in GSR Part 3 [1] and GSR Part 1 (Rev. 1) [14]. Further guidance and recommendations are given in IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [16]. Recommendations on regulatory body roles and responsibilities with respect to occupational radiation protection and radiation protection of the public are given in IAEA Safety Standards Series No. GSG-7, Occupational Radiation Protection [17], and GSG-8 [15], respectively. An important prerequisite for the regulatory body to be able to perform its regulatory functions effectively is having staff with appropriate expertise.

Authorization of inspection devices

2.28. One of the main forms of regulatory control is authorization of facilities and activities; the authorization process is applicable to the use of inspection devices.

2.29. Regulatory bodies should consider which form of authorization — registration or licensing — is appropriate for a given type of inspection device.

The type of authorization will determine the type and level of complexity of the documentation that should be submitted by applicants to the regulatory body prior to the authorization, including the degree of detail in the safety assessment (see paras 2.141–2.146).

2.30. Authorization by registration is best suited to those practices for which operations do not vary significantly. As stated in footnote 19, para. 3.8 of GSR Part 3 [1]:

> "Typical practices that are suitable for registration are those for which: (i) safety can largely be ensured by the design of the facilities and equipment; (ii) the operating procedures are simple to follow; (iii) the training requirements for safety are minimal; and (iv) there is a history of few problems relating to safety in operations."

2.31. While the conditions listed in para. 2.30 would generally be met in the case of some inspection devices, for those inspection devices for which there is the possibility that humans might be inadvertently exposed to radiation, authorization by licensing is more appropriate.

2.32. Irrespective of the form of authorization used for an inspection device, prior to the granting of the authorization, the regulatory body should ascertain that key personnel with responsibilities for radiation protection and safety — including the registrant or licensee, the radiation protection officer and the qualified expert — have the necessary competences.

2.33. Paragraph 4.34 of GSR Part 1 (Rev. 1) [14] states:

> "The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization."

2.34. This includes guidance for use by persons or organizations applying for an authorization to use an inspection device for a practice that has been justified in the State. This should include, if appropriate, guidance on the facility layout, including the designation of inspection zones, controlled areas and supervised areas if applicable; the design of inspection devices; staff education and training; preparation and use of safety assessments; local rules and other procedures for operation; procedures for meeting any conditions stipulated in the justification of the practice; occupational radiation protection (including dose constraints); protection of the public; and any other safety related information.

2.35. Inspection devices may be used in a busy public area such as an airport terminal. The regulatory body should verify, through the authorization process, that all operational aspects of radiation protection, as described in the application for authorization, can be achieved in such an environment.

2.36. In some States, authorizations are subject to periodic review and, if appropriate, renewal after a set time interval. This allows a review of the findings of inspections and of other information on the safety performance of the facility using inspection devices. If the renewal of authorization is applied, the frequency of renewal should be based on protection and safety criteria, with consideration given to the frequency of inspections by the regulatory body and the safety record associated with a given type of practice. The same objective, however, could be achieved through periodic inspections. The regulatory body should apply a graded approach to the authorization review and renewal cycle for facilities using inspection devices.

2.37. The regulatory body should require the registrant or licensee to notify it of any significant changes to safety related aspects, and to apply where necessary for an amendment or renewal of the authorization.

Particular considerations for the regulatory body with respect to occupational exposure

2.38. With respect to the assessment of occupational exposure, Requirement 20 of GSR Part 3 [1] states:

> "**The regulatory body shall establish and enforce requirements for the monitoring and recording of occupational exposures in planned exposure situations.**"

Occupational exposure arising from most practices using inspection devices should be sufficiently low and predictable that they can be assessed on the basis of workplace monitoring. For inspection devices using linear accelerators or gamma sources, the assessment of occupational exposure by individual monitoring may be considered appropriate. The regulatory body might also provide specific guidance for facilities and activities using inspection devices on the assessment of occupational exposure. Further recommendations and guidance on workplace and individual monitoring are given in paras 2.108–2.117.

Authorization for the installation, maintenance and servicing of inspection devices

2.39. The regulatory body should ensure that persons or organizations who install, maintain or service inspection devices are appropriately trained in protection and safety and are authorized. The regulatory approach to engineers and technicians who install inspection devices varies between States. In many States, the installation and servicing are subject to authorization.

Dissemination of information

2.40. Paragraph 2.33 of GSR Part 3 [1] states:

> "The regulatory body shall ensure that mechanisms are in place for the timely dissemination of information to relevant parties…on lessons learned for protection and safety from regulatory experience and operating experience, and from incidents and accidents and the related findings."

In the context of this Safety Guide, the relevant parties include facilities using inspection devices, manufacturers and suppliers of inspection devices, and relevant authorities and organizations.

Responsibilities of the registrant or licensee

2.41. Principle 1 of IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [18], states:

> "**The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.**"

In the context of this Safety Guide, the responsibility for protection and safety rests with the person or organization using an inspection device — normally referred to as the registrant or licensee.

Management system

2.42. Requirement 5 of GSR Part 3 [1] states:

> "**The principal parties shall ensure that protection and safety are effectively integrated into the overall management system of the organizations for which they are responsible.**"

2.43. Paragraphs 2.47–2.52 of GSR Part 3 [1] set out additional requirements on the protection and safety elements of the management system, on the need to promote and maintain safety culture, and on the need to take into account human factors. Further requirements for the management system are given in IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [19], and guidance on their implementation is provided in IAEA Safety Standards Series No. GS-G-3.1, Application of the Management System for Facilities and Activities [20]. The requirements, recommendations and guidance for the management system are provided in these publications and will not be described further in this Safety Guide other than to emphasize that effective management for protection and safety requires commitment at the highest levels of management in the respective organizations, including the provision of the necessary resources.

2.44. The registrant or licensee, through its management system, is responsible for the establishment and implementation of the technical and organizational measures necessary to ensure protection and safety, and for compliance with the relevant legal and regulatory requirements and, where appropriate, authorization conditions. Specific duties and responsibilities for safe operation of the inspection device(s) will typically be assigned to a range of people, including the radiation protection officer and the workers operating inspection devices. All such responsibilities and duties should be identified and documented. In some cases, it may be appropriate to appoint people from outside the organization to carry out tasks or actions in relation to these responsibilities, such as a qualified expert; however, the registrant or licensee retains the prime responsibility for protection and safety and regulatory compliance (see para. 3.13 of GSR Part 3 [1]).

2.45. A senior manager should be assigned responsibility for overseeing protection and safety and for verifying that the practice is carried out in accordance with regulatory requirements. Managers should ensure that procedures are in place for the protection of workers and the public, and for ensuring that protection and safety are optimized. All policies and procedures should be documented and made available to staff and the regulatory body, as appropriate.

2.46. Requirement 12 of GSR Part 2 [19] states:

> "**Individuals in the organization, from senior managers downwards, shall foster a strong safety culture.**"

The aim should be to encourage an open, questioning and learning attitude to protection and safety and to discourage complacency within the organization (see para. 2.51(g) of GSR Part 3 [1]). A strong safety culture is promoted by management arrangements and workers' attitudes, which interact to foster a safe approach to the performance of work. Safety culture is not confined to radiation protection; it should also extend to conventional safety. Management and staff in organizations with a strong safety culture do not assign blame when incidents occur; they encourage a questioning attitude, learn from their mistakes and seek continual improvement in protection and safety.

2.47. The licensee should arrange for the supplier to provide training to relevant staff on the operation and maintenance of the inspection device and the associated inspection system and software.

Radiation protection and safety programme

2.48. The registrant or licensee should develop, document and implement a radiation protection and safety programme, in accordance with Requirement 24 of GSR Part 3 [1]. This programme should include information on the radiation protection arrangements, the measures for implementing the arrangements, and the mechanism for the review and updating of the arrangements. Further details on the radiation protection and safety programme are given in paras 2.76–2.169.

Responsibilities of suppliers

2.49. Suppliers[3] of inspection devices and systems and developers of associated software have responsibilities with respect to protection and safety in terms of the design and performance of the devices (see para. 3.49 of GSR Part 3 [1]). These responsibilities are further described in paras 2.151–2.162.

[3] The definition of supplier (of a source) in GSR Part 3 [1] includes designers, manufacturers, producers, constructors, assemblers, installers, distributors, sellers, importers and exporters of a source.

2.50. A supplier of inspection devices should seek confirmation from the end user that the equipment is to be used in relation to a suitably authorized facility or activity.

2.51. The general requirements for the safety of radiation generators and radioactive sources are given in para. 3.49 of GSR Part 3 [1], which states:

> "Registrants and licensees who are manufacturers or other suppliers of radiation generators and radioactive sources shall ensure that the following responsibilities are discharged, as applicable:
>
> (a) Supplying a well designed, well manufactured and well constructed radiation generator or radioactive source and device in which the radiation generator or radioactive source is used that:
> (i) Provides for protection and safety in accordance with the requirements of [GSR Part 3];
> (ii) Meets engineering, performance and functional specifications;
> (iii) Meets quality standards commensurate with the significance for protection and safety of systems and components, including software;
> (iv) Provides clear displays, gauges and instructions on operating consoles in the appropriate language understandable to users."

2.52. The above requirements are applicable to all inspection devices. Manufacturers and suppliers of inspection devices, whether devices are manufactured in, or imported into, the State in which they are used, are required to ensure that inspection devices conform to any applicable standards of the International Electrotechnical Commission and the International Organization for Standardization and to relevant national standards (see para. 3.67 of GSR Part 3 [1]).

2.53. Inspection devices should have safety features that include:

(a) Radiation beam collimation;
(b) A visual indication, clearly visible from all possible positions of the operator, of when the radiation beam is on;
(c) Safety systems, as appropriate, to prevent inadvertent exposures;
(d) Shielding incorporated into the device to ensure that occupational exposure and public exposure requirements in areas immediately adjacent to the device are met;
(e) Preset operating settings for each mode of operation;

(f) A key operated and/or password protected control panel;
(g) Suitable warning labels or signs incorporating the basic ionizing radiation symbol recommended by the International Organization for Standardization [21];
(h) One or more emergency stop buttons, if applicable.

2.54. Paragraph 3.49(c) of GSR Part 3 [1] places a responsibility on manufacturers and suppliers to make:

> "information available, in the appropriate language understandable to users, on the proper installation and use of the radiation generator or radioactive source and on its associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety."

2.55. A particular issue with inspection devices and associated software is that English and other major languages dominate the language, terminology and icons used on control panels, on software screens and in instruction manuals. Inspection devices are likely to be deployed in any State, and it is important that the device installers, operators and maintenance personnel understand any displays, gauges and instructions on the operating consoles of inspection devices, and also the accompanying instruction and safety manuals. In such cases, the accompanying documents, including maintenance and service manuals and instructions for maintenance and service engineers and technicians, should be translated into the local language. The software should be designed so that it can be easily converted into the local language, resulting in displays, symbols and instructions that will be understood by workers.

Control of radioactive sources

2.56. Some radioactive sources used in inspection devices are capable of causing serious injuries if used incorrectly. The high activity gamma sources described in para. 2.5 are generally considered to be Category 2 and 3 sources in IAEA Safety Standards Series No. RS-G-1.9, Categorization of Radioactive Sources [22], and GSR Part 3 [1]. In comparison, the beta sources described in para. 2.6 are Category 5 sources. Licensees should ensure that sources are kept under proper control from the time the sources are first acquired until they are finally returned to their original supplier or safely dealt with at the end of their lifetime. Internationally endorsed recommendations to States on the safety and security of Category 1, 2 and 3 sources are given in the Code of Conduct on the Safety and Security of Radioactive Sources [23].

2.57. Licensees should ensure that they obtain radioactive sources from authorized suppliers only and that disused sources are returned to the original supplier or transferred to another authorized body. The import and export of radioactive sources should be consistent with the recommendations in the Code of Conduct [23] and the supporting Guidance on the Import and Export of Radioactive Sources [24].

2.58. Licensees are required to conduct periodic inventories of radiation generators and radioactive sources to confirm that the sources are in their assigned locations (see paras 3.53 and 3.55 of GSR Part 3 [1]). Sources should be removed from a source store or moved to another location only by authorized and trained workers. The name of the worker who removed the source should be recorded, together with the date and time, and the exact new location(s) to which the source is being moved. These records should be audited by the radiation protection officer periodically to ensure that the location of all radioactive sources is accounted for. Inspection devices that contain a neutron generator (i.e. that contains a tritium source) should be included in these accountancy procedures.

2.59. Any suspected loss of control over a radioactive source or neutron generator should be promptly investigated by the registrant or licensee. The regulatory body, and any other authority considered to be relevant, should be notified within 24 hours or as otherwise specified in regulatory requirements.

Security of radioactive sources

2.60. The purpose of security measures is to deter, detect, delay and respond to unauthorized access to radioactive sources. Some radioactive sources used in inspection devices are capable of causing serious injuries, and there could be a significant impact if these sources were to be used for malicious purposes. The following paragraphs are intended to raise awareness about the security issues that need to be addressed and that are covered in detail in IAEA Nuclear Security Series publications. In particular, IAEA Nuclear Security Series Nos 20, Objective and Essential Elements of a State's Nuclear Security Regime [25], and 14, Nuclear Security Recommendations on Radioactive Material and Associated Facilities [26], which provide recommendations to States and competent authorities on how to develop or enhance, to implement and to maintain a nuclear security regime for radioactive material, associated facilities and associated activities. IAEA Nuclear Security Series No. 11, Security of Radioactive Sources [27], contains more specific guidance to assist States in the development of regulatory requirements for the security of radioactive sources using a graded approach, based on considerations of the threat, the nature of

the sources and the relative attractiveness of the material for use in a malicious act. Reference [27] suggests using the IAEA's system for categorization of radioactive sources [1, 22] in order to assign a particular security level to sources and to help define the necessary security measures. If the radioactive sources used for inspection imaging purposes are in Categories 1, 2 or 3, then the security measures described in Ref. [27] should be applied. IAEA Nuclear Security Series No. 9, Security in the Transport of Radioactive Material [28], provides guidance on the security of radioactive material during transport.

Safety–security interfaces

2.61. Safety measures and security measures have the common aim of protecting human life, health and the environment. Safety measures and security measures should be designed and implemented in a coordinated manner so that security measures do not compromise safety and safety measures do not compromise security.

2.62. To ensure that safety and security are implemented in a compatible manner, the government may designate a responsible body for managing the interfaces between safety and security in relation to radioactive sources. This may be the regulatory body if the regulatory body has responsibility for both the safety and security of radioactive sources under the regulatory infrastructure.

2.63. In the use of radioactive sources in inspection devices, there may be an interface between safety measures and security measures with regard to access to information. For safety purposes, information on the locations and characteristics of radioactive sources and the safety measures in place may need to be readily accessible. However, this information may also be of potential value to an adversary and therefore security considerations may require that the confidentiality of some sensitive information be protected. Guidance on the protection and confidentiality of sensitive information in nuclear security is provided in IAEA Nuclear Security Series No. 23-G, Security of Nuclear Information [29]. An appropriate balance should be maintained between the availability of information for safety reasons and the need to protect sensitive information for security reasons.

2.64. Control measures to prevent the accidental loss of radioactive sources in inspection devices, which may have security as well as safety implications, are described in paras 2.56–2.60. The primary security concerns are the possibility of unauthorized removal or sabotage of radioactive sources. Effective security

measures will also provide some inherent benefit for safety by preventing accidental loss of control.

2.65. Safety measures intended to prevent the loss of radioactive sources or for protection against radiation incidents in general can also provide some protection against the unauthorized removal or sabotage of those sources. However, the element of intent involved in unauthorized removal or sabotage means that additional considerations apply, especially for higher activity radioactive sources, and additional security measures may be needed to protect against unauthorized removal or sabotage.

APPLICATION OF RADIATION PROTECTION PRINCIPLES

2.66. The three general principles of radiation protection, justification, optimization of protection and safety and the application of dose limits, are expressed in Principles 4–6 of SF-1 [18]. Requirement 1 of GSR Part 3 [1] states that "**Parties with responsibilities for protection and safety shall ensure that the principles of radiation protection are applied**".

Justification

2.67. Requirement 10 of GSR Part 3 [1] requires that a positive net benefit be demonstrated before a practice in a planned exposure situation can be authorized by the regulatory body. Consideration should be given to the way in which inspection devices are to be used in the proposed practice. Specific conditions of use in a proposed practice should be considered in the justification process and, if the practice is ultimately considered justified, such conditions of use should form part of the conditions of the authorization.

2.68. In accordance with para. 4.11 of GSG-5 [4], the application for the justification of a practice should include an assessment of the radiation detriment. This assessment should consider the doses to workers and the public, including potential doses from accidents. For some practices using inspection devices for the detection of contraband in large containers or in vehicles, there is a possibility of members of the public being inadvertently exposed to radiation, and this possibility should be included in the assessment of the radiation detriment. The possible exposure of drivers and passengers in vehicles should also be considered. The application should also contain an appraisal of the benefits of the proposed practice. The benefits of such uses of radiation is clearly for the authorities, but may also be considered in terms of increased security for society at large. With

regard to the inadvertent exposure of concealed persons, in some States it is considered that there is also a benefit to these persons, for example from being released from dangerous circumstances (e.g. risk of suffocation).

Optimization of protection and safety

2.69. Paragraph 1.15 of GSR Part 3 [1] states:

> "The optimization of protection and safety, when applied to the exposure of workers and members of the public…is a process for ensuring that the likelihood and magnitude of exposures and the number of individuals exposed are as low as reasonably achievable, with economic, societal and environmental factors taken into account. This means that the level of protection would be the best possible under the prevailing circumstances."

2.70. Optimization is a prospective and iterative process that requires judgements to be made using both quantitative and qualitative techniques. Optimization should be conducted within a set of boundary conditions, which include individual source related values of dose constraints for occupational exposure and for public exposure. In accordance with para. 1.23 of GSR Part 3 [1]:

> "For occupational exposure, the dose constraint is a tool to be established and used in the optimization of protection and safety by the person or organization responsible for a facility or an activity. For public exposure in planned exposure situations, the government or the regulatory body ensures the establishment or approval of dose constraints".

Dose limits

2.71. Dose limits apply to occupational exposure and public exposure arising from planned exposure situations, including practices involving the use of inspection devices. Schedule III of GSR Part 3 [1] sets out these dose limits, and these are reproduced in Box 1 in the Appendix.

2.72. The dose limits for public exposure apply to individuals who may be inadvertently exposed while inside a cargo container or vehicle.

GRADED APPROACH

2.73. The ‘graded approach’ is a concept that underpins the application of the system for protection and safety. Paragraph 2.12 of GSR Part 3 [1] states:

> “The application of the requirements for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation.”

2.74. GSR Part 3 [1] places responsibilities for a graded approach on each of the government, the regulatory body, registrants and licensees, and employers. The government and the regulatory body use the graded approach in setting and enforcing regulatory requirements, such as the process for justification and for authorization. For example, it would be expected that regulatory bodies devote fewer resources and less time to regulating the use of inspection devices to detect explosives or narcotics in bottles, the use of beta sources for detection of trace quantities of explosives and narcotics, and the use of post room scanners and baggage inspection systems, and more resources and time to regulating the use of inspection devices for cargo screening, where the potential for inadvertent exposure of individuals may occur, and the use of hand-held backscatter units and portable X ray units, and for inspection imaging devices that contain Category 1, 2 or 3 radioactive sources.

2.75. The registrants or licensees, and employers should use a graded approach in the measures they take for protection and safety.

RADIATION PROTECTION AND SAFETY PROGRAMME

2.76. As stated in para. 2.48, the registrant or licensee should 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. The radiation protection and safety programme should include at a minimum the following:

(a) Management structure, commitment and policies (paras 2.77 and 2.78);
(b) Assignment of responsibilities for protection and safety (paras 2.79–2.87);
(c) Education and training (paras 2.88–2.94);
(d) Designation of controlled areas and supervised areas (paras 2.95–2.97);

(e) Arrangements for protection of occupationally exposed workers, including local rules and procedures, monitoring of the workplace, assessment of occupational exposure, and workers' health surveillance (paras 2.98–2.129);
(f) Arrangements for protection of workers driving vehicles undergoing inspection (paras 2.130–2.132);
(g) Arrangements for protection of the public, including members of the public who are inadvertently exposed (paras 2.133–2.140);
(h) Safety of facilities and inspection devices, including safety assessments, accident prevention, design considerations, commissioning and maintenance, and quality assurance programmes (paras 2.141–2.165);
(i) Periodic reviews and audits of the performance of the radiation protection and safety programme (paras 2.166–2.168);
(j) A system for document control and records (para. 2.169).

Management structure and policies

2.77. The radiation protection and safety programme should include the company policies on protection and safety, and should include a commitment by the management to keeping radiation doses as low as reasonably achievable and to promoting a strong safety culture.

2.78. The radiation protection and safety programme should include a description of the management structure as it relates to protection and safety. This structure, which may be presented in the form of an organizational chart, should show the names of the senior managers responsible for radiation protection and safety and the names of the various duty holders (e.g. radiation protection officers). The chart should clearly show the line of reporting, from the workers operating inspection devices through to the senior manager with overall responsibility. If the registrant or licensee has more than one location of operations, the management structure should clearly specify the responsible persons at each location.

Assignment of responsibilities for protection and safety

2.79. Requirement 5 of GSR Part 3 [1] includes a specific requirement for protection and safety to be effectively integrated into the overall management system of a given organization. In addition, paras 2.42 and 2.43 of GSR Part 3 [1] require a "protection and safety programme" in general, and Requirement 24 of GSR Part 3 [1] requires a "radiation protection programme" specifically for occupational exposure. Both of these programmes should be part of the overall management system.

2.80. The general responsibilities of registrants and licensees for protection and safety are given in paras 2.41–2.48. Responsibilities for radiation safety should be assigned to cover the entire lifetime of inspection devices at the facility, from ordering and receipt, use and storage, to their eventual disposal, sale or other end-of-life action. The posts for which responsibilities should be allocated include the management of the registrant or licensee, the radiation protection officer, qualified experts, workers operating inspection devices and other workers as appropriate.

2.81. The purpose of the organization's radiation protection and safety programme is to ensure compliance with GSR Part 3 [1] and national regulatory requirements, and hence ensure the safety of individuals who could be exposed to radiation arising from the use of inspection devices. These individuals include the workers who operate the inspection devices, personnel who work nearby and members of the public. As required by para. 3.93 of GSR Part 3 [1], protection and safety should be achieved through the use of engineered controls (e.g. appropriate equipment and facility designs), and then administrative controls (e.g. policies, procedures and local rules) and training consistent with applicable regulations and standards.

2.82. The registrant or licensee should establish procedures to control access to, and operation of, an inspection device. The registrant or licensee should authorize appropriate personnel to operate the equipment, and control panel keys and/or user password protection should be used to prevent unauthorized operation of the device.

Radiation protection officer and qualified expert

2.83. As defined in GSR Part 3 [1], the radiation protection officer is a "person technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant, licensee or employer to oversee the application of regulatory requirements."

2.84. For a facility using inspection devices, the radiation protection officer oversees the day to day application of the arrangements for protection and safety, and may provide general radiation protection advice. The radiation protection officer should be granted sufficient authority, resources and organizational freedom to effectively oversee the radiation protection and safety programme and, if required, to stop unsafe activities. There may be a need for more than one radiation protection officer to be appointed by the organization, depending on the extent of their operations.

2.85. The registrant or licensee may also need the services of a qualified expert (see para. 2.46 of GSR Part 3 [1]) to perform various radiation protection measurements and to provide expert advice on particular aspects of protection and safety.

2.86. A qualified expert is defined in GSR Part 3 [1] as an "individual who, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization".

2.87. In the context of inspection devices, the qualified expert would be a person with recognized qualifications and experience in radiation protection and safety. The facility's radiation protection officer may be able to fulfil this role, depending on education, training, qualifications and competence.

Education and training

2.88. GSR Part 3 [1] places great emphasis on education and training for all persons engaged in activities relevant to protection and safety. While it assigns responsibility to the government for establishing requirements in this regard, and to the regulatory body for their application, specific responsibilities are also assigned to registrants and licensees.

2.89. Paragraph 2.44 of GSR Part 3 [1] states:

> "The relevant principal parties [the registrant or licensee of the facility using inspection devices] and other parties having specified responsibilities in relation to protection and safety shall ensure that all personnel engaged in activities relevant to protection and safety have appropriate education, training and qualification so that they understand their responsibilities and can perform their duties competently, with appropriate judgement and in accordance with procedures."

2.90. Paragraph 3.110 of GSR Part 3 [1] requires employers to provide workers with "adequate instruction and training and periodic retraining in protection and safety, and adequate information on the significance of their actions for protection and safety" and to "maintain records of the training provided to individual workers."

2.91. The arrangements for keeping training records should be consistent with regulatory requirements and guidance, and they should be specified in the radiation protection and safety programme.

2.92. The radiation protection and safety programme should describe the training programme in protection and safety for all workers directly involved in the management and operation of the inspection devices. The scope and extent of the training should be commensurate with the role and responsibility of the individual involved. The training should include radiation 'awareness', where appropriate, for other workers, such as drivers of vehicles that frequently undergo inspection, security guards and administrative staff. This should be a simplified version of the training provided to operators of inspection devices.

2.93. The radiation protection and safety programme should specify the minimum educational and professional qualifications for relevant staff, especially radiation protection officers and qualified experts, in accordance with regulatory requirements. Specific instruction and training should be provided when new inspection devices and associated equipment and software are introduced. Periodic refresher training should also be provided as part of the radiation protection and safety programme, with additional training when inspection devices, software or procedures are changed. Where appropriate, training on security aspects of the use of radioactive sources should be provided.

2.94. Specific training should be provided for workers who operate inspection devices. At a minimum, this training should include instruction on pre-operational checks, functional tests, safety features, operation of the system, object positioning, interpretation of images, procedures to be followed if the system is damaged or malfunctions, and practical operating experience. In addition, workers who operate inspection devices should be given radiation protection and safety training that includes, at a minimum, the following:

(a) The type and properties of the radiation source and the radiation emitted;
(b) The typical radiation exposures from the normal use of the inspection device and from incidents;
(c) The radiation risk for workers and the public;
(d) The use of design features, time, distance and shielding to reduce exposures;
(e) Lessons identified from operating experience and from incidents;
(f) Safe working procedures, including procedures for emergency preparedness and response.

Designation of controlled areas and supervised areas

2.95. The radiation protection and safety programme should describe where and how controlled areas and supervised areas are to be designated for the use of inspection devices, in accordance with the requirements and criteria for designation of areas given in paras 3.88–3.92 of GSR Part 3 [1].

2.96. In accordance with paras 3.88 and 3.89 of GSR Part 3 [1], the designation of controlled areas is required to be based on the need for protection and safety measures to control exposures, and the need to limit the likelihood and magnitude of potential exposures. In practice, for inspection devices, the need to designate controlled areas and supervised areas will be based on the safety assessment and the dose rates to which workers and the public could be exposed.

2.97. Paragraph 3.90(a) of GSR Part 3 [1] requires that controlled areas be delineated by physical means. For many inspection devices, the controlled area is contained within the immediate cabinet or enclosure. In other cases, delineation of the controlled area can be achieved through the use of barriers, markings on the floor and walls, and suitable warning signs. For large inspection devices, this delineation could be incorporated into the building structure.

Protection of workers

2.98. Occupationally exposed individuals include workers operating inspection devices, service engineers, radiation protection officers and qualified experts performing radiation surveys.

2.99. Facility personnel for whom radiation sources are not required by, or directly related to, their work are required to be provided with the same level of protection as members of the public (para. 3.78 of GSR Part 3 [1]). Consequently, the recommendations provided in paras 2.133–2.140 for the protection of the public are also applicable in respect of such workers.

2.100. Comprehensive recommendations on occupational radiation protection, including guidance on radiation protection programmes and assessment of occupational exposure applicable to all facilities and activities, are provided in GSG-7 [17].

Local rules and procedures

2.101. Paragraph 3.93 of GSR Part 3 [1] establishes a hierarchy of preventive measures for protection and safety with engineered controls being supported by administrative controls and personal protective equipment. As required in para. 3.94 of GSR Part 3 [1], written local rules and procedures are necessary for the use of all inspection devices. The purpose of these local rules and procedures is to ensure protection and safety for workers and the public. Local rules that describe the procedures for operating inspection devices should be developed and written in a language understood by the people who will need to follow them. These local rules should cover all aspects of operating the inspection device relevant to protection and safety.

2.102. Management should ensure that all relevant persons have read and understood the local rules. A copy should be provided to all workers that operate the equipment and other relevant persons, and additional copies should be available in the area in which the inspection device is being used.

2.103. The local rules and procedures should include measures to minimize occupational exposure and public exposure during both normal work and in anticipated operational occurrences and accident conditions. The local rules and procedures should describe the arrangements for wearing, handling and storing personal dosimeters, if used, and specify investigation levels and follow-up actions, as appropriate (see para. 3.94 of GSR Part 3 [1]).

2.104. All workers involved in operating inspection devices need to know and follow the local rules and procedures: it is recommended that the continual improvement of local rules and procedures, based on operating experience, should involve as many of these workers as possible.

2.105. Inspection devices, including both hardware and software, should be operated in a manner that ensures satisfactory performance at all times with respect to the purpose of the inspection and to protection and safety. The operating instructions provided by the manufacturer are an important resource in this respect, but additional procedures are likely to be needed. The registrant or licensee should approve the final set of operating procedures, and the procedures should be documented and incorporated into the registrant's or licensee's management system.

2.106. The registrant or licensee should ensure that workers understand the operating procedures for their work with inspection devices, including

the correct use of any safety features, and that such workers have received appropriate training.

2.107. Pre-operational checks, functional tests and the operation of the inspection device should be described in operational instructions and performed as specified by the manufacturer. The registrant or licensee should establish which checks need to be performed, who will perform them and how the results are to be recorded and interpreted, in accordance with the manufacturer's recommendations.

Monitoring of the workplace

2.108. Paragraphs 3.96–3.98 of GSR Part 3 [1] set out the requirements and responsibilities for workplace monitoring. Workplace monitoring comprises measurements made in and around inspection devices in operation, and the recording and interpretation of the results. Workplace monitoring can be undertaken for several purposes, including routine monitoring, special monitoring for specific activities or tasks, and confirmatory monitoring to check assumptions made about exposure conditions. The facility's radiation protection officer or qualified expert should provide specific advice on the workplace monitoring programme. Further general guidance on workplace monitoring is given in GSG-7 [17].

2.109. Workplace monitoring can be used to estimate occupational exposures, especially of personnel working in areas with low levels of radiation, which is the case with many types of inspection device. Paragraph 3.101 of GSR Part 3 [1] states:

> "For any worker who regularly works in a supervised area or who enters a controlled area only occasionally, the occupational exposure shall be assessed on the basis of the results of workplace monitoring or individual monitoring, as appropriate."

2.110. Workplace monitoring should be carried out in areas around each inspection device in the facility while it is in operation. This monitoring should be carried out:

(a) When the installation has been completed and before the device is first used;
(b) When new software for the inspection device is installed or there is a significant modification or maintenance to the hardware or software;

(c) When servicing that might have an impact on protection and safety has been performed on the inspection device;
(d) If working patterns or other factors change from assumed values.

2.111. The radiation protection and safety programme may include dose rate investigation levels (see para. 3.128 of GSG-7 [17]), set by management, the radiation protection officer or qualified expert, that are the maximum dose rates that are acceptable during the operation of an inspection device, for example at the operator's position and at other specified positions. Such dose rate investigation levels should be consistent with regulatory requirements and guidance. The local rules are required to include any relevant investigation levels and the procedures to be followed in the event that any such level is exceeded (para. 3.94 of GSR Part 3 [1]).

2.112. A programme for the use of workplace monitoring instruments should be specified. The programme should provide information on the recommended frequency of measurements around inspection devices, the details to be recorded and the length of time for which the records should be kept.

2.113. The protection and safety programme should describe the procedures for the selection, calibration, maintenance and testing of workplace monitoring instruments. The instruments used for radiation monitoring should be calibrated in terms of ambient dose equivalent, $H^*(10)$. The frequency of the calibration should be in accordance with regulatory requirements. Records of calibrations should be kept as part of the quality assurance programme.

Assessment of occupational exposure by individual monitoring

2.114. Paragraph 3.100 of GSR Part 3 [1] states:

> "For any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible."

2.115. The purpose of monitoring and dose assessment is to provide information about the actual exposure of workers in order to demonstrate regulatory compliance and to confirm good working practices. Monitoring involves more than just measurement; it also involves interpretation, investigation and reporting, which may lead to corrective measures, if necessary.

2.116. Individual dose monitoring would not normally be expected for a worker using inspection devices, but there might be circumstances in which it might be considered. For example, a new facility using inspection devices may decide to perform individual monitoring for an initial period of time to confirm that the inspection devices are functioning as designed and to provide reassurance to the operators in their new role. For hand-held inspection devices, individual dose monitoring may be appropriate. Periodic individual monitoring may be part of the facility's ongoing quality assurance programme for the inspection devices. As part of the application for an authorization, the registrant or licensee should state whether individual monitoring for occupational exposure is to be carried out.

2.117. The radiation protection officer or qualified expert should review the dose records periodically to identify doses that may be higher than usual and to review whether doses are as low as reasonably achievable. Detailed guidance can be found in GSG-7 [17].

Investigation levels

2.118. Investigation levels are different from dose constraints and dose limits; they are a tool used by managers to initiate a review of procedures and performance, investigate what is not working as expected and take timely corrective action. More detailed guidance on the purpose and use of investigation levels is provided in GSG-7 [17].

2.119. In a facility using inspection devices, occupational exposures are expected to be very low, and hence the investigation level should be set at a correspondingly low value, taking into account the sensitivity of the monitoring device and the period of monitoring. For example, for a three month monitoring period, recorded doses higher than 0.25 mSv should be investigated.

2.120. As described in para. 2.111, investigation levels should also be set for workplace monitoring, for example in terms of ambient dose rate. Abnormal conditions or events should also trigger an investigation. In all cases, the investigation should be carried out to improve the implementation of optimization of protection and safety. The investigation should be performed by the registrant or licensee with the assistance of the facility's radiation protection officer and qualified expert, as appropriate. In some cases, the regulatory body may also need to be informed.

2.121. The investigation should be started as soon as possible following the initiating event and a written report should be prepared, which should include

details of the cause of the event, the determination or verification of the dose(s) received, any corrective or mitigating actions taken, and instructions or recommendations to avoid a recurrence of the event.

Records of occupational exposure

2.122. Paragraphs 3.103–3.107 of GSR Part 3 [1] state the requirements for records of occupational exposure, placing obligations on the employer, registrant and licensee. As well as demonstrating compliance with legal requirements, records of occupational exposure should be used in assessing the effectiveness of the implementation of optimization of protection and safety, and evaluating trends in exposure. The regulatory body might specify additional requirements for records of occupational exposure and for access to the information contained in those records. Further guidance on records of occupational exposure is given in GSG-7 [17].

Workers' health surveillance

2.123. The primary purpose of health surveillance is to assess the initial and continuing fitness of workers for their intended tasks, and requirements are given in paras 3.108 and 3.109 of GSR Part 3 [1].

2.124. Under normal working conditions, the occupational exposures from the use of inspection devices are very low and normally no specific radiation related medical examinations would be required for workers.

2.125. If a programme for periodic health surveillance of workers is considered appropriate, it should be provided by a suitable occupational health service under the direction of an occupational physician, as described in section 10 of GSG-7 [17]. As well as routine health surveillance, these arrangements should also be able to provide counselling to workers, including occupationally exposed female workers who suspect that they are pregnant or who may become pregnant, who are concerned about their radiation exposure.

Conditions of service of workers

2.126. Paragraph 3.111 of GSR Part 3 [1] states:

> "The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure. Special compensatory arrangements, or preferential consideration with respect to salary, special

insurance coverage, working hours, length of vacation, additional holidays or retirement benefits, shall neither be granted nor be used as substitutes for measures for protection and safety".

Arrangements for the protection of female workers

2.127. Paragraph 3.113 of GSR Part 3 [1] states:

> "Employers, in cooperation with registrants and licensees, shall provide female workers who are liable to enter controlled areas or supervised areas…with appropriate information on:
>
> (a) The risk to the embryo or fetus due to exposure of a pregnant woman;
> (b) The importance for a female worker of notifying her employer as soon as possible if she suspects that she is pregnant".

2.128. The purpose of notifying the employer is to enable the working conditions for the female worker to be adapted so as to ensure that the embryo or fetus is afforded the same level of protection as a member of the public. This does not mean that it is necessary for pregnant women to avoid work with radiation, but it does imply that the employer should carefully review the working conditions with regard to both normal exposure and potential exposure. In the case of the use of inspection devices, there should be no need for any change in the duties of a pregnant worker. However, it is recognized that a pregnant woman may have concerns about working with radiation, even where exposures are very low, and, in addition to the information required to be provided by the employer on the risks to the embryo or fetus, access to individual advice, for example from a qualified expert, should also be made available.

Persons under 18

2.129. Paragraph 3.115 of GSR Part 3 [1] requires that "no person under the age of 16 years is or could be subject to occupational exposure." While probably unlikely, a trainee operator aged 16 to 18 years could commence training under supervision to become an operator of an inspection device. Paragraph 3.116 of GSR Part 3 [1] states the requirements for access to controlled areas, and the dose limits for such persons are more restrictive. Box 1 in the Appendix to this Safety Guide reproduces the dose limits from Schedule III of GSR Part 3 [1], including those for apprentices of 16 to 18 years of age.

Protection of workers driving vehicles undergoing inspection

2.130. In normal circumstances, workers driving vehicles undergoing inspection should not be exposed. It is considered that the exposure of workers driving vehicles in such situations is not generally justified, unless specific justification shows that there is a positive net benefit from remaining in the vehicle. Exposure of workers driving vehicles in such situations should not be a matter of operational convenience, and the workers should not be allowed to occupy vehicles during inspection, except in very unusual circumstances [2].

2.131. In the very unusual circumstances in which workers driving vehicles are allowed to occupy vehicles during inspection, all possible measures should be taken to eliminate or reduce the exposures through the use of interlocks and other safety systems to prevent exposure. Even in situations in which interlocks and other devices may prevent the primary radiation beam from exposing such workers, exposure from scattered radiation will need to be considered in the dose assessment. Furthermore, consideration should be given to the possibility of failure of the interlocks or other safety systems intended to prevent exposure. In addition, consideration should be given to the possibility that workers driving vehicles may pass through inspection systems several times per day, rather than assuming that any exposures will be infrequent. All of these considerations should be reflected in specific regulatory requirements and conditions of the authorization issued by the regulatory body.

2.132. In the very unusual circumstance that the exposure of workers driving vehicles is specifically justified and is authorized to occur, such exposure should be treated as occupational exposure. Nevertheless, the dose constraint for such exposure should be set at a level such that the public dose limit is not expected to be exceeded.

Protection of the public

2.133. The radiation protection and safety programme should describe the procedure for periodically estimating the likely doses to members of the public arising from the use of inspection devices. The procedure should include the methodology by which public exposure is estimated, how often this is undertaken and by whom. The radiation protection officer or qualified expert should review the estimated doses to determine whether doses to the public are as low as reasonably achievable.

2.134. Paragraphs 3.117–3.129 and 3.135–3.137 of GSR Part 3 [1] set out the requirements for the protection of the public that are relevant to the use of inspection devices. General guidance on protection of the public can be found in GSG-8 [15].

External exposure

2.135. The primary means for protecting members of the public (and also facility personnel for whom radiation sources are not directly related to their work; see para. 2.99) is to ensure that the shielding integral to the inspection devices, and any structural shielding of the building housing the devices, and any other shielding used when devices are operated is sufficient to ensure that the exposure from being in any accessible adjacent area, including rooms above and below, is in compliance with the public dose limits and below any dose constraint that the regulatory body may have established or approved (see paras 1.23 and 3.120 of GSR Part 3 [1]).

Control of access

2.136. In addition to providing adequate shielding, the registrant or licensee should ensure that access by members of the public (and by facility personnel for whom radiation sources are not directly related to their work: see para. 2.99) to controlled areas and supervised areas, where relevant, is restricted. Registrants and licensees should ensure that there are a limited number of ways to enter a controlled area, and that access is controlled either by engineered controls or by facility personnel. Suitable warning signs should be placed at the entry points stating clearly who is permitted to enter this area.

Monitoring and reporting

2.137. Paragraph 3.137 of GSR Part 3 [1] sets out the requirements to be met by registrants or licensees with respect to monitoring and reporting of public exposure. Procedures should be in place to ensure that:

(a) A monitoring programme for public exposure is established and implemented;
(b) Appropriate records of the results of the monitoring programmes are kept and made available to the regulatory body.

2.138. The programme for monitoring public exposure arising from the use of inspection devices should include an assessment of the doses to persons in areas that are accessible to members of the public. Such an assessment is likely to have

been part of the shielding calculations undertaken at the design stage: this should be reviewed and combined with workplace monitoring results from the initial operation of the device and periodically thereafter.

Protection of the public that may be inadvertently exposed during the inspection process

2.139. Paragraphs 2.130–2.132 provide recommendations and guidance on the protection of drivers at work. In normal circumstances, any other drivers and passengers (i.e. who are not at work) of vehicles undergoing inspection should also not be exposed. In the very unusual circumstance that exposure of such drivers and passengers is specifically justified and authorized to occur, such exposure should be treated as public exposure, and hence the dose limit and dose constraints for public exposure should apply.

2.140. The possible inadvertent exposure of persons concealed or hiding in a cargo container or a vehicle should be considered in the design and operation of the inspection system. The inspection system should be designed and operated so as to ensure that the likelihood of such inadvertent exposure is as low as reasonably achievable and that, if such exposures were to occur, the individual dose to a concealed person would be unlikely to exceed the public dose limit. This should be demonstrated in the safety assessment submitted as part of the justification process and as part of an application for authorization.

Safety of facilities and inspection devices

Safety assessment

2.141. A safety assessment means an assessment of all aspects of radiation protection and safety that are relevant to the inspection devices, including the siting, design and operation of the inspection device and the inspection facility, as appropriate.

2.142. The regulatory body has a responsibility to establish requirements for safety assessment and to review and assess the safety assessment prior to granting an authorization (see Requirement 13 and para. 3.29 of GSR Part 3 [1]). The applicant for an authorization, or the registrant or licensee (see para. 3.30 of GSR Part 3 [1]), is responsible for preparing the safety assessment. Safety assessments are required to be conducted at different stages, as appropriate, including before a facility is operational and when a major change in operation is contemplated (see para. 3.31 of GSR Part 3 [1]).

2.143. Paragraphs 3.30–3.36 of GSR Part 3 [1] provide requirements on the content of a safety assessment, the factors that the registrant or licensee is required to take into account when preparing the safety assessment, the documentation and placement of the safety assessment in the management system, and when additional reviews of the safety assessment need to take place. More detailed requirements on safety assessment for facilities and activities are given in IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities [30]. For inspection devices, the safety assessment should include not only considerations of occupational and public exposure, but also the exposure of persons who may be inadvertently exposed and the possibility of accidental exposures. In the case of vehicle or cargo scanners, the safety assessment should consider the possible exposure of drivers, passengers and concealed individuals, as appropriate.

2.144. GSR Part 3 [1] specifies two types of safety assessment — generic or specific to the practice or source. As stated in footnote 29, para. 3.30 of GSR Part 3 [1]:

> "A generic safety assessment is usually sufficient for types of source with a high degree of uniformity in design. A specific safety assessment is usually required in other cases; however, the specific safety assessment need not include those aspects covered by a generic safety assessment, if a generic safety assessment has been conducted for the type of source."

2.145. The safety assessments needed in the context of the use of inspection devices will range in complexity, but even if an inspection device is covered by a generic safety assessment, the way it is used may need to be considered in some form of specific safety assessment.

2.146. The safety assessment should provide a basis for decision making in relation to the following:

(a) The engineered control measures that are required for safety;
(b) The development of local rules and procedures to be followed by workers operating inspection devices;
(c) Requirements and procedures for designating controlled areas and supervised areas;
(d) Any requirements for protection of persons inside the cargo container or vehicles;
(e) Any requirements for protection of workers and the public;
(f) The measures required to minimize the likelihood of incidents occurring;

(g) Emergency plans, including the actions to be taken to restrict exposure of persons and for protection of the environment.

Prevention of accidents

2.147. Accident prevention is the best means for avoiding potential exposure, and paras 3.39–3.42 of GSR Part 3 [1] set out requirements for good engineering practice, defence in depth and accident prevention. Design considerations for inspection facilities are described in paras 2.151–2.154.

2.148. For inspection devices, possible scenarios for potential exposure include flaws in the design of the device, failures of engineered controls on inspection devices while in operation, failures and errors in the software that control or influence the emission of radiation from the inspection device, and human error.

2.149. The registrant or licensee should establish procedures for workers to follow in the event of malfunction of, or damage to, an inspection device. Normally, the inspection device should be removed from operational use until appropriate maintenance or service engineers have corrected the problem and, if appropriate, a qualified expert has performed a radiation survey. The procedures should specify the actions or testing necessary before the inspection device is returned into use following repairs or adjustments.

2.150. Inadvertent, accidental or unauthorized entry to a controlled area represents another scenario for potential exposure of workers or the public. Accident prevention by control of access is described in para. 2.136.

Design of the facility

2.151. Paragraph 3.51 of GSR Part 3 [1] sets out the general safety requirements that need to be met when choosing a location and designing a facility for using inspection devices. Provisions for the incorporation of safety features are best made during the design stage of the facility. The siting and layout of the facility should take into account the occupancy of adjacent areas, dose rates and doses per scan, workload, system orientation (i.e. beam direction), the flow of people and, if relevant, vehicles.

2.152. Where practicable, the design of the inspection device should be such that it incorporates all the necessary shielding to ensure that occupational exposure and public exposure arising from its use in normal operation will be well below the relevant dose limits and will meet the applicable dose constraints. Additional

structural shielding may be required for inspection devices that produce high dose rates, such as accelerators, high energy X ray generators, some gamma sources and some neutron generators. Details about the design of such shielding can be found in Refs [21, 31].

2.153. The design of the device and/or facility should provide a suitable means for exit, so that any person inadvertently remaining in a room or enclosure containing an X ray generator, accelerator or radioactive source can make a prompt exit.

2.154. Signs and warning lights, preferably positioned at eye level, should be positioned at the entrances of any controlled areas, as appropriate, to prevent inadvertent entry (see also para. 2.136 on control of access). For controlled areas, para. 3.90(c) of GSR Part 3 [1] requires that registrants and licensees display the basic ionizing radiation symbol recommended by the International Organization for Standardization [21] at entrance points and at appropriate locations within the controlled area. All signs should be clear and easily understandable. Warning signals, such as illuminated or flashing lights or signs, should be activated when radiation is being produced.

Installation, commissioning, testing and maintenance of inspection devices

2.155. Paragraphs 3.15(i) and 3.41 of GSR Part 3 [1] include requirements for maintenance and testing to ensure that inspection devices meet their design requirements for protection and safety throughout their lifetime and to prevent accidents as far as reasonably practicable.

2.156. Inspection devices should be installed in accordance with the manufacturer's instructions and the installation should comply with relevant regulatory requirements and authorization conditions. As noted in para. 2.39, only properly trained and authorized individuals should be allowed to install inspection devices.

2.157. During installation, the designation of any controlled and supervised areas should be confirmed and documented. Controlled areas should be clearly delineated, as described in para. 2.97.

2.158. Acceptance tests should be performed for new or modified or repaired devices, or after the installation of new software or the modification of existing software that could affect protection and safety. Depending on the agreement between the manufacturer or supplier and the end user, acceptance tests can

be performed by the manufacturer's representative in the presence of the radiation protection officer or qualified expert representing the user, or by a radiation protection officer or qualified expert jointly with the manufacturer's representative. Whatever the case, the arrangements should be agreed in advance and it should be ensured that the process involves the verification of all specifications and features of the device relevant to protection and safety.

2.159. After satisfactory completion of the acceptance tests and before the inspection device is put into use, commissioning tests should be carried out by, or under the supervision of, the radiation protection officer or qualified expert. Commissioning should include measurements of all parameters and conditions of use that are expected in operation. For many inspection devices, there may be little difference between acceptance tests and commissioning. As part of the commissioning, the baseline for subsequent constancy tests should be established. The registrant or licensee should ensure that the performance of the inspection device meets regulatory requirements and any conditions of the authorization. In addition, a qualified expert should perform a radiation survey of the inspection device and, if applicable, the inspection facility to verify that protection and safety are optimized.

2.160. After installation of inspection devices or software, the supplier should conduct a formal handover to the registrant or licensee. This handover should include testing to verify that the inspection device and software are performing to the required standards (see para. 3.49(a) of GSR Part 3 [1]) and specific training in the use of the device and software for the workers involved in operating the device. The features of the device and software should be fully understood, including their implications for protection and safety. A written report by the installation engineer detailing the post-installation performance results should be provided to the licensee before the device is put into use.

2.161. The registrant or licensee should ensure that adequate maintenance (preventive and corrective) is performed as necessary to ensure that inspection devices retain, or improve through appropriate hardware and/or software upgrades, their design specifications for protection and safety for their full lifetime. The registrant or licensee should, therefore, establish the necessary arrangements and coordination with the manufacturer's representative and/or installer before initial operation and on an ongoing basis thereafter.

2.162. Maintenance procedures should be carried out at the frequency recommended by the manufacturer of the device. Maintenance records should be kept for each device: these records should include information on any defects

found by users (a fault log), remedial actions taken (both interim and subsequent repairs) and the results of testing before a device is reintroduced into use.

Quality assurance programme

2.163. A quality assurance programme for the use of inspection devices should be established and should include documentation, radiation monitoring, quality control tests, training, records, a preventive maintenance programme, and a review of local rules and procedures. The quality assurance programme should be designed to ensure that all equipment and safety systems are regularly subjected to quality control tests, and that any faults or deficiencies are brought to the attention of the management and are promptly remedied. The purpose of the quality control tests is to ensure that, at all times, all inspection devices are performing correctly, accurately, reproducibly and predictably. The quality control programme should include the establishment of a baseline set of measurements to be taken at the acceptance testing stage (see para. 2.158).

2.164. The regulatory body may have its own specific requirements on the quality control tests that need to be performed and their frequencies.

2.165. The regulatory body should review the records of the quality assurance programme during inspections of facilities and activities using inspection devices.

Periodic reviews and audits of the performance of the radiation protection and safety programme

2.166. As an integral part of the registrant's or licensee's management system, the radiation protection and safety programme, and its implementation should be reviewed on a regular basis. This periodic review by independent colleagues (not involved in the development of the part of the management system being reviewed) should verify that the management system is fit for purpose, identify any problems that need to be addressed and any modifications that could improve the effectiveness of the radiation protection and safety programme, as well as assess the effectiveness of corrective actions taken.

2.167. Factors to be considered include the selection and qualification of the persons who will conduct the internal reviews, the frequency of reviews, the expectations of the review team, the procedures for reporting of results and their follow-up.

2.168. A key part of this periodic review process is a routine series of audits. Factors to be considered include the selection and qualification of the persons who will conduct the audits, the frequency of audits, the expectations of the audit team, the procedures for reporting of results and their follow-up.

Records

2.169. Records are an important part of demonstrating ongoing compliance with radiation protection requirements. For inspection devices, such records include:

(a) Use and maintenance logs: Records of upgrades, modifications, maintenance and repair should be maintained for the life of the inspection devices (paras 2.155–2.157).
(b) Quality assurance programme records: Records of all aspects of the quality assurance programme, including acceptance tests, quality control tests and preventive maintenance programme (paras 2.163–2.165).
(c) Training records: Records of all training, including the date of training, an outline of the training and the names of those in attendance (paras 2.88–2.94).
(d) Radiation monitoring: Records of individual monitoring and workplace monitoring, and reports of any investigations and public dose assessment (paras 2.108–2.117).
(e) Events: Records of any near misses or events, including the corrective actions taken.

The records should be kept for the period specified by the regulatory body.

MANAGEMENT OF DISUSED SEALED RADIOACTIVE SOURCES

2.170. The registrant or licensee should review its inventory of radioactive sources at least annually to identify any sources that are not in routine use and have become disused.

2.171. Paragraph 3.60 of GSR Part 3 [1] states:

> "Registrants and licensees shall ensure that arrangements are made promptly for the safe management of and control over radiation generators and radioactive sources, including appropriate financial provision, once it has been decided to take them out of use."

2.172. The registrant or licensee should meet any regulatory requirements for reporting disused sources. The registrant and licensee should also comply with the national requirements with regard to the disposal of disused radioactive sources.

2.173. Registrants or licensees with inspection devices containing radioactive sources should seek an agreement with the supplier of the devices at the time of purchase that disused sources can be returned to the supplier. If such an agreement does not exist, the registrant or licensee should ensure that there are appropriate arrangements for the transfer of the sources to another licensed operator with proper and adequate facilities for the conditioning, storage and disposal of the disused radioactive sources as radioactive waste. These arrangements should include the provision of adequate financial resources to cover the costs associated with waste management.

2.174. The regulatory body should pay specific attention to situations involving disused sealed sources that cannot be returned to the supplier or manufacturer. In such cases, the regulatory body should give consideration to the identification and authorization of an appropriate organization that is equipped to manage disused radioactive sources safely. This may include the transfer of disused sources to an authorized waste management facility.

2.175. The management of disused sealed radioactive sources (i.e. by the operator of the centralized disused source conditioning facility) can involve potentially serious hazards. As a general principle, sealed sources should not be removed from their primary containers, nor should the container be physically modified. Peripheral components not directly associated with the source should be removed, monitored and disposed of appropriately.

2.176. The most important consideration in the management of sealed sources, once the sealed sources are no longer useful, is the maintenance of continuity of control. Provisions should be made by the registrant or licensee and, where appropriate, the regulatory body to maintain that continuity and periodically revisit the status of control of disused sealed radioactive sources.

2.177. Further guidance is provided in IAEA Safety Standards Series No. SSG-45, Predisposal Management of Radioactive Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education [32].

Transport of inspection devices that contain radioactive material

2.178. Paragraph 2.25 of GSR Part 3 [1] states:

> "The government shall ensure that the transport of radioactive material is in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material (the IAEA Transport Regulations) [(see Ref. [33])] and with any applicable international conventions".

2.179. When radioactive sources are transported between States, the Code of Conduct on the Safety and Security of Radioactive Sources [23] and the supporting Guidance on the Import and Export of Radioactive Sources [24] should also be observed.

2.180. IAEA Safety Standards Series No. SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material, 2018 Edition [33], contains detailed requirements; the regulations should be consulted directly to ensure that all applicable requirements are met.

2.181. Local rules for transport operations should include arrangements for ensuring the security of the consignment during breaks in the journey, such as rest and overnight stops, and contingency plans for dealing with reasonably foreseeable events, such as traffic accidents.

INVESTIGATION OF EVENTS

2.182. All relevant staff should be adequately trained to be able to recognize when an inspection device may not be functioning correctly, either due to hardware or software problems.

2.183. If an event that is significant for protection and safety occurs, the registrant or licensee should conduct an investigation, the aim of which is:

(a) To determine the root cause of the event;
(b) To estimate the doses received by the exposed persons (i.e. workers and members of the public), as applicable;
(c) To ensure that any exposed persons are informed about the accidental exposure;
(d) To identify and implement any corrective actions necessary to prevent the recurrence of such an event.

2.184. The registrant or licensee should produce a written record that contains the information specified above, as relevant, and any other information required by the regulatory body. This should be done as soon as possible after the investigation or as otherwise required by the regulatory body. For significant accidental exposures, or as otherwise required by the regulatory body, this written record should be submitted to the regulatory body as soon as possible. A copy should be kept by the registrant or licensee.

EMERGENCY PREPAREDNESS AND RESPONSE

2.185. The registrant or licensee should put in place arrangements for emergency preparedness and response, including plans that are to be implemented in the event of an emergency. Plans should be provided to cover all reasonably foreseeable scenarios, including those of very low probability.

2.186. Arrangements for emergency preparedness and response should be established and maintained on the basis of the hazards associated with the radiation source used in the inspection device. These arrangements should be consistent with the requirements of IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [34]; and the guidance in IAEA Safety Standards Series Nos GS-G-2.1, Arrangements for Preparedness for a Nuclear or Radiological Emergency [35], GSG-2, Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency [36], and GSG-11, Arrangements for the Termination of a Nuclear or Radiological Emergency [37].

2.187. All workers operating inspection devices should be aware of the indicators of a potential radiological emergency and be adequately trained to take appropriate actions, as given in the emergency plan.

2.188. After the situation has been brought under control and the necessary actions have been implemented, the registrant or licensee should investigate the circumstances under which the emergency occurred and analyse the emergency response with the involvement of interested parties. This investigation should be used:

(a) To determine the root cause of the emergency;
(b) To estimate the doses received by the exposed persons (e.g. workers, emergency workers and members of the public), as applicable;

(c) To identify and implement any corrective actions necessary to prevent the recurrence of such an emergency;
(d) To assess the efficiency of the emergency response actions taken;
(e) To identify necessary improvements to regulatory control;
(f) To identify necessary improvements to the emergency arrangements.

2.189. The registrant or licensee should produce a written record that contains the information specified above, as relevant, and any other information required by the regulatory body. This should be done as soon as possible after the investigation or as otherwise required by the regulatory body. For significant accidental exposures, or as otherwise required by the regulatory body, this written record should be submitted to the regulatory body as soon as possible. A copy should be kept by the registrant or licensee.

3. THE USE OF X RAY GENERATORS FOR NON-MEDICAL HUMAN IMAGING

TYPES OF EQUIPMENT USED FOR NON-MEDICAL HUMAN IMAGING

3.1. Category 1 non-medical human imaging procedures are performed using medical radiological equipment, as defined in GSR Part 3 [1]. The type of medical radiological equipment used includes radiography X ray units, dental X ray units and computed tomography (CT) scanners. The justification process for any Category 1 non-medical human imaging procedure under consideration should specify the types of radiological medical equipment intended to be used.

3.2. Category 2 non-medical human imaging procedures are performed using inspection imaging devices, as defined in GSR Part 3 [1]. Two different types of ionizing radiation technology are used: transmission technology and backscatter technology. With transmission technology, an image is obtained by the radiation passing through the body of the person being imaged. Such an image will display objects concealed on the body and also those concealed within the body. Doses from transmission based inspection imaging devices are typically in the range of 2–5 μSv per scan. With backscatter technology, an image is formed from the radiation scattered from the surface of the person being imaged, and such an image will display only objects concealed on the body (e.g. hidden in or under clothing). Doses from backscatter based inspection devices are lower than doses

from transmission based inspection devices; typically less than 0.1 μSv per image. The images from backscatter imaging include details of the anatomical features of the person being inspected and privacy concerns need to be considered. The software of inspection imaging devices is capable of addressing such concerns and this option should be considered. Employing same gender operators as the individual undergoing the procedure should also be considered. Privacy and cultural issues should be considered as part of the overall justification process.

3.3. In addition to the type of technology, inspection 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' [38, 39], which are defined as follows:

(a) General use systems are characterized by a very low dose per exposure, typically an effective dose of less than 0.1 μSv per scan. 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. Such systems would be based on backscatter technology.
(b) Limited use systems are characterized by delivering a higher dose per exposure, 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. Consequently, administrative and operational 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, limited use systems should be used with discretion in terms of the selection of individuals to be scanned and the number of scans per individual per year.

3.4. A Category 2 non-medical human imaging procedure may involve more than one scan and produce more than one image.

FRAMEWORK FOR RADIATION PROTECTION AND SAFETY FOR NON-MEDICAL HUMAN IMAGING

Responsibilities of the government

3.5. The roles and responsibilities of the government[4] with regard to protection and safety are set out in Requirement 2 and paras 2.13–2.28 of GSR Part 3 [1], with further detailed requirements given in GSR Part 1 (Rev. 1) [14]. These include the following:

(a) Establishing an effective legal and regulatory framework for protection and safety for all exposure situations.
(b) Establishing legislation that meets specified requirements.
(c) Establishing an independent regulatory body with the necessary legal authority, competence and resources.
(d) Establishing requirements for education and training in protection and safety.
(e) Ensuring that arrangements are in place for the provision of:
    (i) Technical services in relation to protection and safety, such as services for personal dosimetry, environmental monitoring, and the calibration of monitoring and measuring equipment;
    (ii) Education and training services.

All of these are relevant to the safe use of ionizing radiation in non-medical human imaging.

Responsibilities of the government or regulatory body

3.6. GSG-5 [4] provides recommendations to governments and regulatory bodies on the approach that should be adopted in considering whether the introduction of a particular type of practice in a planned exposure situation is justified.

3.7. As stated in para. 1.9, it is assumed in this Safety Guide that an effective governmental, legal and regulatory infrastructure for radiation protection and safety is in place. However, there are some additional considerations that are important for ensuring radiation protection and safety in the use of ionizing radiation for non-medical human imaging.

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[4] States have different legal structures and therefore the term ‘government’, as used in the IAEA safety standards, is to be understood in a broad sense, and is accordingly interchangeable here with the term ‘State’.

3.8. The role of the government is important in terms of establishing the legal and regulatory framework for non-medical human imaging. The government should ensure that the relevant government ministries and authorities work in a coordinated manner, particularly with respect to justification and the conditions associated with any justified practice, providing a framework for implementation, including a policy for the regulatory body to follow.

3.9. GSR Part 3 [1] takes the default position that most non-medical human imaging procedures are normally considered to be not justified. However, GSR Part 3 [1] recognizes that there might be exceptional circumstances in which justification of such imaging might be considered for specific practices. In such cases, there are specific requirements that then apply to ensure an appropriate framework for radiation protection. The responsibility for deciding whether practices involving human imaging are justified rests with the government or the regulatory body. In the specific case of human imaging for the detection of concealed objects that could be used for criminal acts that pose a national security threat, the responsibility for justification lies with government only (para. 3.21 of GSR Part 3 [1]).

3.10. Requirement 18 of GSR Part 3 [1] states:

> "**The government shall ensure that the use of ionizing radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research is subject to the system of protection and safety.**"

3.11. As stated in para. 3.64(a) of GSR Part 3 [1], for Category 1 non-medical human imaging procedures that have been justified:

> "The government shall ensure, on the basis of consultation between relevant authorities, professional bodies and the regulatory body, that dose constraints are established for such human imaging".

3.12. Relevant authorities are likely to include the health authority and the ministry under whose jurisdiction the non-medical human imaging purpose falls, for example the ministries of justice, of immigration or of labour. In setting dose constraints, the particular imaging requirements need to be considered. In some cases, the imaging requirements will be the same as for an equivalent medical diagnostic procedure. In such cases, typical patient doses and national diagnostic reference levels would be two considerations in setting dose constraints. In other situations, lower image quality may be sufficient to reliably achieve the

purpose of the procedure. For example, a CT scan of the abdomen to detect drugs concealed within the body is likely to require a lower dose than a routine diagnostic CT scan of the abdomen.

3.13. In accordance with para. 3.120 of GSR Part 3 [1], the government or the regulatory body is required to establish or approve dose constraints for public exposure. This includes persons who undergo Category 2 non-medical human imaging. The exposure of such persons is considered to be public exposure in a planned exposure situation (para. 3.65 of GSR Part 3 [1]), and hence is also subject to the dose limits for public exposure.

3.14. One purpose of the dose constraint for public exposure is to ensure that the sum of doses from planned operations for all sources under control remains within the dose limit. One approach that can be taken is to set a dose constraint for public exposure arising from a single facility at some fraction of the dose limit. Some States use a dose constraint of approximately one third or one quarter of the dose limit for public exposure. In establishing or approving such a value, the government or regulatory body should consider the number and type of radiation sources in use in a particular State or region to which the public may be exposed. In the case of Category 2 non-medical human imaging procedures undertaken for security screening, some States have recommended a dose constraint of 0.25 mSv per year in terms of the cumulative dose to any one individual at a given security screening facility [38].

Responsibilities of the regulatory body

3.15. The functions of the regulatory body, such as establishing regulations and guides, authorizing and inspecting facilities and activities, and enforcing regulatory requirements, are described in GSR Part 3 [1] and GSR Part 1 (Rev. 1) [14]. Further recommendations are given in GSG-13 [16]. Recommendations on regulatory body roles and responsibilities with respect to occupational radiation protection and radiation protection of the public are given in GSG-7 [17] and GSG-8 [15], respectively.

3.16. An important prerequisite for the regulatory body to be able to perform its regulatory functions effectively is having staff with appropriate expertise. This is particularly important in the context of the justification of non-medical human imaging in that people are deliberately exposed to radiation, sometimes without their knowledge, and often with no obvious individual benefit from the exposure.

3.17. Paragraph 3.62 of GSR Part 3 [1] states:

> "If it has been determined…that a particular practice of human imaging using radiation is justified, then such a practice shall be subject to regulatory control."

3.18. Furthermore, para. 3.63 of GSR Part 3 [1] states:

> "The regulatory body, in cooperation with other relevant authorities, agencies and professional bodies, as appropriate, shall establish the requirements for regulatory control of the practice and for review of the justification."

Regulatory controls for Category 1 non-medical human imaging

3.19. One of the main forms of regulatory control is authorization of facilities and activities. In those States in which Category 1 non-medical human imaging is considered to be justified, the regulatory body should consider whether a specific authorization is required to carry out non-medical human imaging procedures in a particular medical facility. Such an authorization should consider the process for justification of the procedure for specific individuals, the training of the staff in relation to the types of procedure to be performed, and the imaging protocols to be used for the procedures to be performed.

3.20. The regulatory body should consider the transition from the generic justification of a particular non-medical human imaging procedure to its implementation for individual persons and situations. The conditions around the generic approval should specify the process for making an individual request for a Category 1 non-medical human imaging procedure. This may be based on legislation or regulations; that is, the generic justification for a given type of Category 1 non-medical human imaging, and the procedures to be followed in its implementation may be described in specific legislation or else brought into the general regulatory framework for facilities and activities. In some States, legislation or regulations[5] establish the procedures that allow X rays to be taken of suspected drug offenders. This legislation specifies that non-medical human imaging for the purpose of drug detection is allowed to be performed (i.e. the State has justified this practice) and also specifies the conditions and procedures that must be followed in applying this to a particular individual. A similar approach could be taken for other Category 1 non-medical human

[5] See, for example: United Kingdom, Drugs Act 2005, 2005 Chapter 17, Part 2, and The Swedish Code of Judicial Procedure, DS1998:000.

imaging purposes, such as obtaining legal evidence (plaintiff or defendant), age determination and immigration purposes.

3.21. The normal regulatory activities of the regulatory body with respect to medical radiation facilities performing radiological procedures for medical diagnosis will apply to Category 1 non-medical human imaging, and extensive guidance on this is given in SSG-46 [3]. During inspections of medical radiation facilities, regulatory body personnel should ascertain whether Category 1 non-medical human imaging procedures are performed in the medical radiation facility and, if so, should ascertain that appropriate imaging protocols are being used for such procedures.

Regulatory controls for Category 2 non-medical human imaging practices

3.22. Regulatory bodies should consider which form of authorization — registration or licensing — is appropriate for a given type of Category 2 non-medical human imaging practice. The type of authorization will determine the type and level of complexity of the documentation that should be submitted by applicants to the regulatory body prior to the authorization, including the degree of detail in the safety assessment (see paras 3.215–3.220).

3.23. Authorization by registration is best suited to those practices for which operations do not vary significantly. As stated in footnote 19, para. 3.8 of GSR Part 3 [1]:

> "Typical practices that are suitable for registration are those for which: (i) safety can largely be ensured by the design of the facilities and equipment; (ii) the operating procedures are simple to follow; (iii) the training requirements for safety are minimal; and (iv) there is a history of few problems relating to safety in operations."

3.24. While the conditions listed in para. 3.23 would generally be met by a Category 2 non-medical human imaging practice, the added consideration that individuals are being deliberately exposed to radiation under the supervision of personnel who are not medically qualified, indicates that a greater degree of regulatory oversight is appropriate. Hence, authorization by licensing is more appropriate.

3.25. Irrespective of the form of authorization used for a Category 2 non-medical human imaging practice, prior to the granting of the authorization, the regulatory body should ascertain that key personnel with responsibilities for radiation

protection and safety — including the registrant or licensee, the radiation protection officer and the qualified expert — have the necessary competences.

3.26. Paragraph 4.34 of GSR Part 1 (Rev. 1) [14] states:

> "The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization."

3.27. This includes guidance for use by persons or organizations applying for an authorization for a Category 2 non-medical human imaging practice that has been justified in the State. If appropriate, the guidance might include, as appropriate, requirements for: the facility layout, including the designation of controlled areas and supervised areas if applicable; the design of inspection imaging devices; staff education and training; preparation and use of safety assessments; local rules and other procedures for operation; procedures for meeting any conditions stipulated in the justification of the practice; occupational radiation protection (including dose constraints); protection of the public, including persons undergoing imaging procedures; and any other safety related information.

3.28. A Category 2 non-medical human imaging facility may be located in a busy public area such as an airport terminal. The regulatory body should verify, through the authorization process, that all operational aspects of radiation protection can be achieved in such an environment.

3.29. In some States, authorizations are subject to periodic review and, if appropriate, renewal after a set time interval. This allows a review of the findings of inspections and of other information on the safety performance of the Category 2 non-medical human imaging facility. If the renewal of authorization is applied, the frequency of renewal should be based on protection and safety criteria, with consideration given to the frequency of inspections by the regulatory body and the safety record associated with a given type of practice.

3.30. The regulatory body should require the registrant or licensee to notify it of any significant changes to safety related aspects, and to apply where necessary for an amendment or renewal of the authorization.

Inspection of non-medical human imaging facilities

3.31. On-site inspection by the regulatory body is often the principal means for face to face contact with personnel in the non-medical human imaging facility.

The regulatory body should establish a system for prioritization and frequency of inspections, based on the risk and complexity associated with the particular uses of ionizing radiation. The inspection of non-medical human imaging facilities should be performed by regulatory body staff with the specialist expertise to competently assess the compliance of the non-medical human imaging practice with regulatory requirements and authorization conditions. Further guidance on inspections by the regulatory body can be found in GSG-13 [16].

Particular considerations for the regulatory body with respect to occupational exposure

3.32. With respect to the assessment of occupational exposure in non-medical human imaging, Requirement 20 of GSR Part 3 [1] states:

> "**The regulatory body shall establish and enforce requirements for the monitoring and recording of occupational exposures in planned exposure situations.**"

Paragraphs 3.99–3.102 of GSR Part 3 [1] require employers, registrants and licensees to make arrangements for occupational exposure assessment, and the requirements indicate when individual monitoring is needed and when workplace monitoring may be sufficient. With respect to Category 1 non-medical human imaging, it is expected that the existing arrangements for assessing occupational exposure (i.e. received by medical staff) will be applied. Occupational exposure arising from a Category 2 non-medical human imaging practice should be sufficiently low and predictable that workplace monitoring would normally suffice. The regulatory body should provide specific guidance for those Category 2 non-medical human imaging practices that have been justified by the State on the assessment of occupational exposure. Further recommendations and guidance on workplace and individual monitoring are given in paras 3.172–3.182.

Authorization for the installation, maintenance and servicing of inspection imaging devices for non-medical human imaging

3.33. The regulatory body should ensure that persons or organizations who install, maintain or service inspection imaging devices are appropriately trained in protection and safety and are authorized. The regulatory approach to engineers and technicians who install inspection imaging devices varies between States. In many States, the engineers and technicians are subject to authorization, and a prerequisite to obtaining such an authorization is appropriate training in protection and safety. The responsibilities for suppliers of sources, equipment

and software, and for maintenance and servicing organizations, are set out in paras 3.48–3.54.

Dissemination of information

3.34. Paragraph 2.33 of GSR Part 3 [1] states:

> "The regulatory body shall ensure that mechanisms are in place for the timely dissemination of information to relevant parties…on lessons learned for protection and safety from regulatory experience and operating experience, and from incidents and accidents and the related findings."

In the context of this Safety Guide, the relevant parties include non-medical human imaging facilities, manufacturers and suppliers of inspection imaging devices, and relevant authorities and organizations.

Responsibilities of the registrant or licensee

3.35. Principle 1 of SF-1 [18] states:

> "**The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.**"

In the context of this Safety Guide, the responsibility for protection and safety rests with the person or organization responsible for the operation of the Category 1 or Category 2 non-medical human imaging facility — normally referred to as the registrant or licensee.

3.36. Category 1 non-medical human imaging procedures are performed in a medical radiation facility. Typically, such a medical radiation facility will be authorized to use radiation sources for medical diagnosis; however, Category 1 non-medical human imaging practices should warrant additional consideration. For example, the registrant or licensee should put in place arrangements to ensure that personnel in the medical radiation facility know when an individual is undergoing a Category 1 non-medical human imaging procedure in order that procedures appropriate to the Category 1 non-medical human imaging are followed.

3.37. The roles and responsibilities within a medical radiation facility described in SSG-46 [3] for medical uses of ionizing radiation are also applicable to

Category 1 non-medical human imaging, with the exception of the responsibility for justification of the procedure. Guidance on the justification of Category 1 non-medical human imaging procedures is provided in paras 3.57–3.102.

Management system

3.38. Requirement 5 of GSR Part 3 [1] states:

> "**The principal parties shall ensure that protection and safety are effectively integrated into the overall management system of the organizations for which they are responsible.**"

3.39. For Category 1 non-medical human imaging procedures, the principal parties referred to above can include the government department or other organizations with responsibilities for enabling the use of the non-medical human imaging procedures, as well as the medical radiation facility on which the imaging procedure is undertaken. For Category 2 non-medical human imaging procedures, the principal parties include the government department or other organizations with responsibilities for enabling the use of the non-medical human imaging procedures, the organization authorized to conduct the non-medical human imaging procedures and the facility in which the imaging is undertaken.

3.40. Paragraphs 2.47–2.52 of GSR Part 3 [1] set out additional requirements on the protection and safety elements of the management system, on the need to promote and maintain safety culture, and on the need to take into account human factors. Further requirements for the management system are given in GSR Part 2 [19], and guidance on their implementation is provided in GS-G-3.1 [20]. The requirements, recommendations and guidance for the management system are provided in these publications and will not be described further in this Safety Guide other than to emphasize that effective management for protection and safety requires commitment at the highest levels of management in the respective organizations, including the provision of the necessary resources.

3.41. Organizations with responsibilities for enabling the use of Category 1 non-medical human imaging procedures should describe the process for enabling such procedures in their management system. This should include processes for obtaining expert advice on protection and safety issues (i.e. if such expertise is not already within the organization) and for selecting medical radiation facilities in which the Category 1 non-medical human imaging procedures are undertaken.

3.42. The overall responsibility for radiation protection and safety lies with the registrant or licensee. Specific duties and the day to day responsibilities for safe operation of the equipment will typically be assigned to a range of people, including senior management, the radiation protection officer, the qualified expert, and inspection device operators and associated staff. All responsibilities and duties should be identified and documented.

3.43. The registrant or licensee, through its management system, is responsible for the establishment and implementation of the technical and organizational measures necessary to ensure protection and safety, and for compliance with the relevant legal and regulatory requirements and, where appropriate, authorization conditions. In some cases, it may be appropriate to appoint people from outside the organization to carry out tasks or actions in relation to these responsibilities, such as a qualified expert; however, the registrant or licensee retains the prime responsibility for protection and safety and regulatory compliance (see para. 3.13 of GSR Part 3 [1]).

3.44. A senior manager should be assigned responsibility for overseeing protection and safety and for verifying that non-medical human imaging procedures are carried out in accordance with regulatory requirements. Managers should ensure that procedures are in place for the protection of workers and the public, including individuals undergoing imaging, and for ensuring that protection and safety are optimized. All policies and procedures should be documented and made available to staff and the regulatory body, as appropriate.

3.45. Requirement 12 of GSR Part 2 [19] states:

> "**Individuals in the organization, from senior managers downwards, shall foster a strong safety culture.**"

The aim should be to encourage an open, questioning and learning attitude to protection and safety and to discourage complacency within the organization (see para. 2.51(g) of GSR Part 3 [1]). A strong safety culture is promoted by management arrangements and workers' attitudes, which interact to foster a safe approach to the performance of work. Safety culture is not confined to radiation protection; it should also extend to conventional safety. Management and staff in organizations with a strong safety culture do not assign blame when incidents occur; they encourage a questioning attitude, learn from their mistakes and seek continual improvement in protection and safety.

3.46. The licensee should arrange for the supplier to provide training to relevant staff on the operation and maintenance of the inspection imaging device and the associated inspection system and software.

Radiation protection and safety programme

3.47. The registrant or licensee is required to develop, document and implement a radiation protection and safety programme, in accordance with Requirement 24 of GSR Part 3 [1]. This programme should include information on the radiation protection arrangements, the measures for implementing the arrangements, and the mechanism for the review and updating of the arrangements. Further details on the radiation protection and safety programme are given in paras 3.132–3.241.

Responsibilities of suppliers

Category 1 practices

3.48. The responsibilities of suppliers of medical radiological equipment are set out in SSG-46 [3].

Category 2 practices

3.49. Suppliers[6] of inspection imaging devices and systems and developers of associated software have responsibilities with respect to protection and safety in terms of the design and performance of the devices (see para. 3.49 of GSR Part 3 [1]). These responsibilities are further described in paras 3.222–3.232.

3.50. A particular issue with inspection imaging devices and associated software is that English and other major languages dominate the language, terminology and icons used on control panels, on software screens and in instruction manuals. However, it is crucial that the person using the equipment or software fully understands the options being presented, and translation into a local language should be arranged.

3.51. Applicable standards at the time of this publication are standards from the International Electrotechnical Commission [40, 41] and the American National Standards Institute [38]. Paragraph 3.49 of GSR Part 3 [1] also provides general

[6] The definition of supplier (of a source) in GSR Part 3 [1] includes designers, manufacturers, producers, constructors, assemblers, installers, distributors, sellers, importers and exporters of a source.

radiation safety requirements for radiation generators and radioactive sources, which are applicable to inspection imaging devices.

3.52. Inspection imaging devices should have safety features that include:

(a) Radiation beam collimation;
(b) A visual indication, clearly visible from all possible positions of the operator, of when the radiation beam is on;
(c) Safety systems, as appropriate, to prevent inadvertent exposures;
(d) Shielding incorporated into the device to ensure that occupational exposure and public exposure requirements in areas immediately adjacent to the device are met;
(e) Preset operating settings for each mode of operation;
(f) A key operated and/or password protected control panel;
(g) An accurately controlled and reproducible dose per exposure for each mode to ensure it meets performance specifications in the authorization;
(h) Suitable warning labels or signs incorporating the basic ionizing radiation symbol recommended by the International Organization for Standardization [21];
(i) One or more emergency stop buttons, if applicable.

3.53. Paragraph 3.49(c) of GSR Part 3 [1] places a responsibility on manufacturers and suppliers to make:

> "information available, in the appropriate language understandable to users, on the proper installation and use of the radiation generator or radioactive source and on its associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety."

3.54. Inspection imaging devices for non-medical human imaging could potentially be deployed in any State, and it is important that the device installers, operators and maintenance personnel understand any displays, gauges and instructions on the operating consoles of inspection devices, and also the accompanying instruction and safety manuals. In such cases, the accompanying documents, including maintenance and service manuals and instructions for maintenance and service engineers and technicians, should be translated into the local language. The software should be designed so that it can be easily converted into the local language, resulting in displays, symbols and instructions that will be understood by workers.

APPLICATION OF RADIATION PROTECTION PRINCIPLES

3.55. The three general principles of radiation protection, justification, optimization of protection and safety and the application of dose limits, are expressed in Principles 4–6 of SF-1 [18]. Requirement 1 of GSR Part 3 [1] states that "**Parties with responsibilities for protection and safety shall ensure that the principles of radiation protection are applied**".

3.56. The responsibility for justification of a type of non-medical human imaging procedure lies with the government or the regulatory body (Requirement 10 of GSR Part 3 [1]), while the registrant or licensee of the facility performing the non-medical human imaging procedures is responsible for optimization of protection and safety and the application of dose limits.

Justification

3.57. Human imaging for artistic or publicity purposes (para. 3.17(c) of GSR Part 3 [1]) or human imaging for theft detection purposes (para. 3.19 of GSR Part 3 [1]) are considered to be not justified.

3.58. The application of the justification principle to non-medical human imaging for other purposes requires a special approach, as required by para. 3.61 of GSR Part 3 [1], which states:

> "The justification process shall include the consideration of:
>
> (a) The benefits and detriments of implementing the type of human imaging procedure;
> (b) The benefits and detriments of not implementing the type of human imaging procedure;
> (c) Any legal or ethical issues associated with the introduction of the type of human imaging procedure;
> (d) The effectiveness and suitability of the type of human imaging procedure, including the appropriateness of the radiation equipment for the intended use;
> (e) The availability of sufficient resources to conduct the human imaging procedure safely throughout the intended period of the practice."

3.59. The government has the responsibility to ensure that these considerations are taken into account in the justification process for any non-medical human imaging practice. Such considerations need to be taken into account because,

unlike medical uses of radiation, non-medical human imaging practices do not yield a direct health benefit to the exposed individual. For such practices, there may be benefits to the exposed individual, but there are also wider benefits to society that should be considered. The onus is on the government to ensure that, as a result of the process in para. 3.61 of GSR Part 3 [1], the proposed non-medical human imaging practice is indeed justified in the wider context; that is, on the basis that it produces a positive net benefit either to the exposed individuals or to society [4].

3.60. As noted in para. 5.16 of GSG-5 [4], if a particular type of practice involving non-medical human imaging is considered to be justified, separate 'levels' of justification should be applied in respect of particular applications of the technique. For example, the generic 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 level of justification. Approving the use of such imaging procedures in specific facilities (or types of facility) represents a second level of justification, although often levels one and two will be considered together. Proposals for application of the technique in other types of facility or situation, such as access control to buildings, should necessitate separate considerations of justification. In this way, the undue proliferation of non-medical imaging can be avoided.

3.61. As noted in para. 5.17 of GSG-5 [4], a further level 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 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.

3.62. Paragraph 3.66 of GSR Part 3 [1] states:

> "Registrants and licensees shall ensure that all persons who are to undergo procedures with inspection imaging devices in which ionizing radiation is used are informed of the possibility of requesting the use of an alternative inspection technique that does not use ionizing radiation, where available."

3.63. Where no alternative inspection technique is available, it should be stated in the application for justification whether the intention is for the procedure using ionizing radiation to be made mandatory or whether it should be subject to the informed consent of the persons who undergo the inspection.

3.64. The justification process should also give consideration to what are acceptable imaging procedures for the proposed practice. For example, the imaging procedure may be limited to a particular modality or part of the body, such as a CT scan of the abdomen, or there may be several options to choose from, or the choice of imaging procedures for an individual case depends on what is required for that case. In the latter two cases, the selection of the appropriate imaging procedure should be subject to a further justification for the individual.

3.65. When a particular practice of non-medical human imaging has been determined to be justified, it will normally be subject to conditions that will need to be fulfilled in the implementation of the practice. For Category 1 non-medical human imaging practices, these conditions should include the requirement that the performance of an individually justified non-medical human imaging procedure should take place in a medical radiation facility that is authorized to use radiation for medical diagnosis.

Justification of Category 1 practices

3.66. The following paragraphs provide a list of possible Category 1 non-medical human imaging practices, and a description of some of the issues that should be considered in the justification process. Listing these practices, together with the associated descriptions, should not be interpreted as indicating that the practices are justified by a State.

3.67. Some of the information below is taken from GSG-5 [4], which also provides additional guidance on the justification process.

Legal purposes: Obtaining legal evidence

3.68. This practice relates to human images being obtained to establish the presence or absence of diseases or injuries to be used in official court proceedings.

3.69. If such imaging is being considered, the State should have a legal mechanism to allow the acquisition of images for the purposes of obtaining legal evidence. The criteria for selection or eligibility of individuals to undergo such imaging would also need to be considered in the justification process, as would the specification of acceptable imaging procedures.

3.70. The parties involved in the justification process for non-medical human imaging for the purpose of obtaining legal evidence would typically include

the authorities for justice and police, medical professional bodies and the regulatory body.

Legal purposes: Age determination

3.71. The reason for examinations to determine age usually originates from some legal circumstance in which there is no valid proof of date of birth. The reason may concern adoption, refugees seeking asylum or be in support of a decision on whether to apply an adult criminal law. Two types of examination are usually carried out: dental and skeletal. A skeletal examination is normally of a selected part of the body, such as the hand and wrist, iliac crest or clavicle.

3.72. The justification process should consider the reasons for undertaking the practice. The main benefit of such examinations is to the authorities in the State where the examinations are performed, to enable a sound basis for a legal decision to be established. There may or may not be a direct benefit to the person being examined.

3.73. Radiological scanning for age determination is not always accurate and should be justified in each case (see paras 3.60 and 3.61). There are many reasons (e.g. socioeconomic) for differences in dental and skeletal development, and the validity of the method to be used should be established for each individual case [42]. Many methods are less accurate for adolescents than for children, and even less accurate for adults. As such, this practice might not be sufficiently accurate for determining whether a persons is, for example, over 18 years of age [42].

3.74. The parties involved in the justification process for non-medical human imaging for the purpose of age determination would typically include the authorities for justice, border control and immigration, medical professional bodies and the regulatory body.

Legal purposes: Immigration or emigration

3.75. X ray examinations can be used to check for active or past disease. The most common example is the use of chest radiographs to determine whether immigrants or emigrants have active or past tuberculosis. This type of practice involves the examination of individuals without medical symptoms. As indicated in paragraph 3.18 of GSR Part 3 [1], automatic examinations without reference to clinical indications are normally deemed not to be justified. However, issues in relation to the protection of the public health and vulnerable individuals

within society may result in the consideration of such practices as necessary for ensuring public health, and hence whether immigration or emigration can take place for an individual.

3.76. If non-medical human imaging procedures for immigration or emigration purposes are being considered by a State, the justification process should also involve a review of the proposed referral or selection criteria to be applied as part of the proposed practice. The onus is on the State to pursue alternative and equivalent means, where available, for achieving the desired outcome. For example, rather than requiring a chest X ray for all immigrants, the immigration requirements could instead require a medical examination, with the need for a chest X ray being determined as a result of the medical examination. Such chest X rays would then be medical exposure and outside the scope of this Safety Guide.

3.77. Non-medical human imaging for immigration purposes poses additional legal issues. If a State has decided that such a practice is justified, it will involve the exposure of persons who are not yet (and who may never become) citizens of that State. Similarly, for any exposures that are undertaken for the purposes of emigration, the justification process should consider how any requirements of the State of destination will be met and the justification for such exposures in that State.

3.78. The consequences of a positive identification of disease should also be considered as part of the justification process. For example, a justification decision may be required in relation to a proposal that all immigrants from States in which tuberculosis is endemic are X rayed to determine whether they have active or past tuberculosis. One possible outcome is that they are treated if a positive diagnosis is made. Another possible outcome is that a positive identification of disease is regarded as a barrier to entry or acts as a trigger for deportation. These are two very different outcomes for the individual who will be X rayed and need to be factored into the decision making process for justification of the procedure.

3.79. The parties involved in the justification process for non-medical human imaging for immigration or emigration purposes would typically include the authorities for immigration and emigration, justice and border control, medical professional bodies and the regulatory body.

Legal purposes: Detection of drugs within a person

3.80. This practice relates to the use of X ray imaging to detect drugs that are concealed within a person entering a State. Packages containing drugs may have been swallowed or otherwise concealed internally by a drug courier transporting them. Non-medical human imaging procedures should be used only when there is a high degree of suspicion that the individual has swallowed a package containing drugs, and particularly when there are concerns for the health of the individual (see para. 3.61). Criteria for identifying suspected drug couriers should be developed.

3.81. The benefit of this procedure is the reduction in trafficking of drugs. In some States, it is considered that there is benefit to the person being examined, in that swallowed drug packages may split and release the content into the intestines, resulting in serious injury or death. In that sense, the exposure could be regarded as being undertaken for medical purposes; however, since the primary purpose is to detect trafficking of drugs, the exposure should not be regarded as a medical exposure unless there are clinical indications for the investigation.

3.82. If such imaging is being considered, the implication is that there will be a legal mechanism whereby the State, typically through a court order or an approved process, can request the acquisition of images for the purposes of detection of concealed drugs. It should be noted that alternative techniques not involving the use of radiation are available, such as the administration of emetics or taking the person into custody for a period of time that would allow for suspected concealed packages to pass through the body.

3.83. The criteria for selection or eligibility of suspected couriers to undergo non-medical human imaging should also be considered, as well as the option for such individuals to undergo an alternative process for ascertaining whether or not drugs are present. The specification of acceptable imaging procedures should also take place.

3.84. As noted in para. 5.50 of GSG-5 [4], the detection of drugs within a person can also be carried out using a transmission X ray scanner (i.e. as a Category 2 practice). Such X ray scans are performed and the images viewed by personnel who are not specialists in radiology, for example by law enforcement officers trained to use such equipment. The effective dose to the person being scanned would be much lower than if it were conducted as a Category 1 procedure. The Category 2 procedures can be used, for example, to scan suspected drug couriers to determine whether further medical examination is required at a medical

facility. Such an approach is consistent with the application of the principle of optimization of protection and safety as discussed in paras 3.120–3.128.

3.85. The parties involved in the justification process for non-medical human imaging for the purpose of detection of drugs within a person would typically include the authorities for justice, border control and police, radiology professional bodies and the regulatory body.

Occupational purposes: Assessment of fitness for employment

3.86. Non-medical human imaging for the assessment of fitness for employment includes imaging performed prior to employment or periodically during employment, where the imaging occurs solely on the basis of an administrative process within a given company or organization. Any imaging performed with reference to clinical indications of the individual is medical exposure and is outside the scope of this Safety Guide.

3.87. Paragraph 3.18 of GSR Part 3 [1] states (footnote omitted):

> "Human imaging using radiation that is performed for occupational, legal or health insurance purposes, and is undertaken without reference to clinical indication, shall normally be deemed to be not justified."

In exceptional circumstances, the government or regulatory body may decide that the justification of such non-medical human imaging for specific practices is justified.

3.88. The onus should be on the State to pursue alternative and equivalent means, where available, for achieving the desired outcome. For example, rather than an administrative order for a chest X ray to be required in all cases, there could instead be a requirement for a medical examination, with any need for a chest X ray being determined as a result of the medical examination.

3.89. If there are deemed to be exceptional circumstances as indicated in para. 3.87, the justification process should consider the specific types of occupation for which justification might be appropriate and any other conditions that would apply to the use of non-medical human imaging for assessment of fitness for employment. The justification process should also consider the specification of acceptable imaging procedures.

3.90. As part of the justification process, it is useful to consider the reasons for undertaking the practice, including any (perceived) benefits. As well as benefits to the employer (which alone should not be a reason for justification), there may also be benefits for workers in terms of general health and safety in the workplace, as well as the early detection of medical problems before symptoms emerge.

3.91. If such imaging is to be allowed, the State should have a legal mechanism whereby individual employers can require employees and prospective employees to undergo X ray examinations for the purpose of assessing fitness for employment without reference to clinical indications.

3.92. The parties involved in the justification process for non-medical human imaging for the purpose of assessment of fitness for employment would typically include the authorities for labour, worker unions and other organizations, medical professional bodies and the regulatory body.

Use of non-medical human imaging for employment in sport or the performing arts

3.93. Non-medical human imaging includes assessment of physiological suitability for a career in sport or the performing arts, and assessment of the health status of athletes before selection or transfer. In all of these cases, the imaging is being initiated on the basis of a sports organization or performing arts organization wishing to obtain the desired information for their benefit. There may also be a benefit to the individual, but this is not the primary reason for the assessment.

3.94. The use of imaging in sports medicine, based on clinical indications of the athlete, is well established and is clearly part of medical exposure because the result (either positive or negative) will influence patient management. Such usage is outside the scope of this Safety Guide.

3.95. As noted in para. 3.87, non-medical human imaging for occupational purposes without reference to clinical indication is not normally justified. In between these two scenarios are imaging procedures that are performed in order to exclude physical abnormalities that would contraindicate participation in certain sports, such as neck abnormalities for young people playing contact sports. Such imaging should be on the basis of medical examination, followed by imaging as indicated by medical conditions, in which case the imaging is medical exposure and would be outside the scope of this Safety Guide. However, if such imaging were based solely on non-medical criteria (e.g. age), then it

would be non-medical human imaging, and the government or regulatory body should decide whether exceptional circumstances warranted the justification of the practice.

3.96. As part of the justification process, it is useful to consider the reasons for undertaking the procedures and, in particular, which parties benefit from the practice and what are the individual consequences for examined athletes or artists. Ethical issues, such as discrimination, should also be considered.

3.97. The parties involved in the justification process for non-medical human imaging for the purpose of assessment of physiological suitability or fitness for selection or transfer would typically include the authorities for labour, sport and recreation, arts, sports organizations, arts organizations, player or performer associations, medical professional bodies and the regulatory body.

Health insurance purposes

3.98. Non-medical human imaging for health insurance purposes includes pre-insurance checks and checks during the lifetime of an insurance policy. Examples could include assessing the significance of pre-existing disorders or checking for the occurrence of subsequent disorders. In all cases, the imaging is being initiated at the request of a health insurance company wishing to obtain information for their own purposes.

3.99. Paragraph 3.18 of GSR Part 3 [1] establishes that non-medical human imaging for health insurance purposes is not justified, except under exceptional circumstances in which the government or regulatory body decides that use of imaging for specific practices can be justified. In such circumstances, the justification process should consider the specific types of health insurance purpose for which justification might be appropriate and any other conditions that would apply to the use of non-medical human imaging for such a purpose. The criteria for selection or eligibility of individuals to undergo imaging for health insurance purposes should also be considered in the justification process. The justification process should also consider the specification of acceptable imaging procedures.

3.100. As part of the justification process, it is useful to consider the reasons for undertaking the procedures and, in particular, which parties benefit from the practice. Non-medical human imaging for health insurance purposes is likely to involve commercial enterprises, with the company accruing the benefit from such exposures. Health insurance is about assessment of risk and non-medical

human imaging procedures are intended to provide the insurers with information to manage the risk in favour of the insurers.

3.101. If such imaging is to be allowed, the State should have a legal mechanism whereby individual health insurance companies can require policy holders and prospective policy holders to undergo X ray examinations for the purpose of providing medical information to the health insurer without reference to clinical indications. Consideration should also be given to whether there would be any restrictions on the health insurance companies that would be eligible.

3.102. The parties involved in the justification process for non-medical human imaging for health insurance purposes would typically include the authorities for health, justice and labour, health insurance companies, consumer representatives, medical professional bodies and the regulatory body.

Justification of Category 2 practices

3.103. In the justification process, the government or regulatory body should consider which type of imaging technology might be acceptable for the proposed practice: transmission technology or backscatter technology (see para. 3.2). Consideration should also be given to the way in which the inspection imaging devices are to be deployed in the proposed Category 2 non-medical human imaging practice; that is, as either a general use system or a limited use system (see para. 3.3).

3.104. Specific conditions of use in a proposed Category 2 non-medical human imaging practice should be considered in the justification process and, if the practice is ultimately considered justified, such conditions of use should form part of the conditions of the authorization.

3.105. The person or organization applying for a Category 2 practice to be justified should undertake a radiological assessment that determines the individual dose per inspection or scan as well as the cumulative dose to persons who are likely to be exposed frequently, for example frequent air travellers, flight crew and ground crew, or frequent visitors to prisons.

3.106. Issues relating to privacy, provision of information to individuals to be screened, selection criteria for individuals to be screened and informed consent should be considered in the justification process, while noting that alternative methods not involving the use of radiation can also involve many of the same issues.

3.107. Consideration of alternative methods does not imply that only one method can ultimately be considered as justified. Several methods may indeed be considered acceptable. In particular, the availability of an acceptable alternative that does not use radiation does not necessarily exclude a radiation based technology as also being justified and acceptable.

3.108. When a particular practice of non-medical human imaging has been determined to be justified, it will normally be subject to conditions that will need to be fulfilled in the implementation of the practice. These conditions should include criteria to be met by a facility seeking authorization for the given Category 2 non-medical human imaging practice.

3.109. Paragraphs 3.110–3.119 present some issues that are pertinent to the justification process for two possible examples of Category 2 non-medical human imaging. Listing these practices, together with the associated descriptions, should not be interpreted as indicating that the practices are justified.

Detection of concealed objects that can be used for criminal acts that pose a security threat

3.110. Commonly referred to as 'security screening', this Category 2 practice is a non-medical human imaging procedure performed on the basis of security considerations. Many scenarios are conceivable and potential applications include passengers boarding aircraft, persons crossing a national border and visitors to prisons. Concealed objects of interest include explosives, firearms, knives and other weapons. Each of these applications, and any others, should be considered separately if being considered for justification by the government in accordance with para. 3.21 of GSR Part 3 [1].

3.111. As part of the justification process, it is useful to consider the reasons why the proposed practice is to be undertaken and which parties will benefit. For these types of practice, the benefit generally lies in preventing the use of explosives and weapons and improving security overall through a deterrent effect. The benefits will be to society in general, although in the case of airline passengers, each passenger may be considered to directly benefit, as well as individual benefits in terms of increased passenger confidence [4]. In any case, each type of security screening application should be specifically evaluated in terms of the purpose and the environment within which the practice is to be applied.

3.112. An example of detailed guidance on the justification process for security screening is given in Ref. [43], and includes the following steps:

(a) Defining the need;
(b) Evaluating the options, including their effectiveness and their limitations;
(c) Evaluating privacy concerns;
(d) Assessing the radiation risk from the technologies;
(e) Assessing the potential net benefit from implementation of the technologies;
(f) Assessing the cost and availability of resources (regulatory, operational and training), and the viability of sustainable implementation.

3.113. The justification process should involve all relevant government authorities, including, but not limited to, those authorities with responsibility for security, border control, consumer groups and the regulatory body. For practices for which a large number of people might be affected, such as the security screening of airline passengers, the government should carefully consider the need for extensive public consultation.

3.114. In the case of the security screening of airline passengers, the government should also consider liaising with counterparts in other States in view of the international dimension of air travel.

3.115. The benefits from some of these types of practice could be substantial. Nevertheless, proposals to introduce them into a State should be scrutinized very carefully by the government.

3.116. When a particular Category 2 non-medical human imaging practice has been considered as justified for a given security purpose within a specified environment, the justification decision should be reviewed on a regular basis as technologies[7] and threat evaluations constantly change.

Detection of concealed objects for anti-smuggling purposes

3.117. This Category 2 practice relates to the use of inspection devices to detect objects that have been deliberately concealed on or in a person because either it is illegal to possess the objects or to avoid paying duties or taxes on the objects. The objects that might be under consideration may differ from State to State, but could include drugs and gemstones. As noted in para. 3.84, in the justification

[7] Inspection imaging devices that use millimetre wave technology have become available in recent years.

process for drug detection, a State may well consider both Category 1 non-medical human imaging and Category 2 non-medical human imaging options.

3.118. As part of the justification process, it is useful to consider the reasons for undertaking the procedures and, in particular, which parties benefit from the practice. The introduction of such a practice in a State may bring societal benefits, including a reduction in the availability of contraband through the detection and confiscation of contraband, and through the deterrence of potential smugglers.

3.119. The parties involved in the justification process for Category 2 non-medical human imaging for anti-smuggling purposes would typically include the authorities for justice, border control, customs, police and the regulatory body.

Optimization of protection and safety

3.120. Paragraph 1.15 of GSR Part 3 [1] states:

> "The optimization of protection and safety, when applied to the exposure of workers and members of the public…is a process for ensuring that the likelihood and magnitude of exposures and the number of individuals exposed are as low as reasonably achievable, with economic, societal and environmental factors taken into account. This means that the level of protection would be the best possible under the prevailing circumstances."

3.121. Optimization is a prospective and iterative process that requires judgements to be made using both qualitative and quantitative techniques. Optimization should be conducted within a set of boundary conditions, which include individual source related values of dose constraints for occupational exposure and for public exposure. In accordance with para. 1.23 of GSR Part 3 [1]:

> "For occupational exposure, the dose constraint is a tool to be established and used in the optimization of protection and safety by the person or organization responsible for a facility or an activity. For public exposure in planned exposure situations, the government or the regulatory body ensures the establishment or approval of dose constraints".

Category 1 practices

3.122. The optimization of protection and safety in relation to occupational exposure and public exposure for Category 1 non-medical human imaging procedures is covered by the application of the principle in relation to medical

uses of ionizing radiation, as described in detail in SSG-46 [3]. In terms of occupational exposure, there is no difference in the performance of a Category 1 non-medical human imaging procedure and a medical radiological procedure — the same requirements and recommendations apply.

3.123. The requirements for the application of the principle of optimization of protection and safety to the exposure of persons undergoing Category 1 non-medical human imaging procedures are specified in para. 3.64(b) of GSR Part 3 [1]. The individual undergoing the Category 1 non-medical human imaging procedure is to be afforded at least the same level of protection and safety as if they were a patient undergoing a similar radiological procedure. Detailed guidance on optimization of protection for patients undergoing radiological procedures is given in SSG-46 [3].

3.124. The objective for each non-medical imaging procedure should be defined. In some cases, the imaging protocols will be the same as for an equivalent medical diagnostic procedure. In other cases, lower image quality might be sufficient to reliably achieve the purpose of the procedure. It is also possible (although less likely) that a higher image quality than that needed for a comparable medical exposure is necessary. Specific protocols, consistent with the objective of the exposure and the image quality that is needed, should be put in place. In all cases, the exposure should be optimized consistent with the need to achieve the purpose of the specific imaging procedure.

Category 2 practices

3.125. Each Category 2 non-medical human imaging procedure should be performed in such a way as to optimize the protection and safety of the person being imaged. Much of this optimization will be achieved through the design of the equipment (see paras 3.223–3.288). The set-up and operation of the equipment are equally important, for example in terms of the device setting options available to the operator. If there are different operating or exposure modes available, the option that results in the lowest exposure consistent with adequate image quality should be used.

3.126. The establishment of dose constraints for persons undergoing Category 2 non-medical human imaging is described in paras 3.12–3.14. Dose constraints are also applicable to occupational exposure (e.g. operators of inspection imaging devices) and to exposure of other members of the public (i.e. those who are not undergoing an imaging procedure).

3.127. As noted in para. 3.14, the dose constraint for each source of radiation exposure is intended to ensure that the sum of doses from planned operations for all sources under control remains within the dose limits. In addition, as stated in para. 1.22 of GSR Part 3 [1]:

> "Dose constraints…serve as boundary conditions in defining the range of options for the purposes of optimization of protection and safety. Dose constraints are not dose limits: exceeding a dose constraint does not represent non-compliance with regulatory requirements, but it could result in follow-up actions."

3.128. Other tools used in the optimization of protection and safety, especially with respect to persons being imaged, include design and operational considerations, calibration, dosimetry and quality assurance programmes. These are described in more detail later in this section.

Dose limits

3.129. Dose limits apply to occupational exposure and public exposure arising from planned exposure situations, including non-medical human imaging applications. Schedule III of GSR Part 3 [1] sets out these dose limits, and these are reproduced in Box 1 in the Appendix.

3.130. Dose limits do not apply to individuals undergoing Category 1 non-medical human imaging procedures that have been justified within a given State.

3.131. The dose limits for public exposure apply to individuals undergoing Category 2 non-medical human imaging procedures that have been justified within a given State.

RADIATION PROTECTION AND SAFETY PROGRAMME

3.132. As stated in para. 3.47, 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. The radiation protection and safety programme should include at a minimum the following:

(a) Management structure, commitment and policies (paras 3.133 and 3.134);

(b) Assignment of responsibilities for protection and safety (paras 3.135–3.144);
(c) Education and training (paras 3.145–3.156);
(d) Designation of controlled areas and supervised areas (paras 3.157–3.160);
(e) Arrangements for protection of occupationally exposed workers, including local rules and procedures, monitoring of the workplace, assessment of occupational exposure, and workers' health surveillance (paras 3.161–3.194);
(f) Arrangements for protection of persons undergoing non-medical human imaging (paras 3.195–3.204);
(g) Arrangements for protection of the public, including assessment of public exposure (paras 3.205–3.211);
(h) Safety of facilities and equipment used for non-medical human imaging, including safety assessments, accident prevention, design considerations, commissioning and maintenance, and quality assurance programmes (paras 3.212–3.235);
(i) Periodic reviews and audits of the performance of the radiation protection and safety programme (paras 3.236–3.238);
(j) A system for document control and records (paras 3.239–3.241).

Management structure and policies

3.133. The radiation protection and safety programme should include the company policies on protection and safety, and should include a commitment by the management to keeping radiation doses as low as reasonably achievable and to promoting a strong safety culture.

3.134. The radiation protection and safety programme should include a description of the management structure as it relates to protection and safety. This structure, which may be presented in the form of an organizational chart, should show the names of the senior managers responsible for radiation protection and safety and the names of the various duty holders (e.g. radiation protection officers). The chart should clearly show the line of reporting, from the workers operating inspection imaging devices through to the senior manager with overall responsibility. If the registrant or licensee has more than one location of operations, the management structure should clearly specify the responsible persons at each location.

Assignment of responsibilities for protection and safety

3.135. Requirement 5 of GSR Part 3 [1] includes a specific requirement for protection and safety to be effectively integrated into the overall management system of a given organization. In addition, paras 2.42 and 2.43

of GSR Part 3 [1] require a "protection and safety programme" in general, and Requirement 24 of GSR Part 3 [1] requires a "radiation protection programme" specifically for occupational exposure. Both of these programmes should be part of the overall management system of the organization responsible for non-medical human imaging.

3.136. The general responsibilities of registrants and licensees for protection and safety are given in paras 3.35–3.47. Responsibilities for radiation safety should be assigned to cover the entire lifetime of inspection imaging devices at the facility, from ordering and receipt, use and storage, to their eventual disposal, sale or other end-of-life action. The posts for which responsibilities should be allocated include the management of the registrant or licensee, the radiation protection officer, qualified experts, workers operating inspection imaging devices and other workers as appropriate.

Category 1 practices

3.137. As Category 1 non-medical human imaging procedures are carried out in a medical radiation facility, guidance on the assignment of responsibilities is provided in SSG-46 [3]. The radiation protection officer of the medical radiation facility oversees the application of the requirements for protection and safety.

Category 2 practices

3.138. The purpose of the organization's radiation protection and safety programme is to ensure compliance with GSR Part 3 [1] and national regulatory requirements, and hence ensure the safety of individuals who could be exposed to radiation arising from the use of Category 2 non-medical human imaging procedures. These individuals include the workers who operate the inspection imaging devices, personnel who work nearby, individuals who undergo imaging procedures and members of the general public. As required by para. 3.93 of GSR Part 3 [1], protection and safety should be achieved through the use of engineered controls (e.g. appropriate equipment and facility designs), and then administrative controls (e.g. policies, procedures and local rules) and training consistent with applicable regulations and standards.

3.139. The registrant or licensee should establish procedures to control access to, and operation of, an inspection imaging device. The registrant or licensee should authorize appropriate personnel to operate the equipment, and control panel keys and/or user password protection should be used to prevent unauthorized operation of the device.

Radiation protection officer and qualified experts

3.140. As defined in GSR Part 3 [1], the radiation protection officer is a "person technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant, licensee or employer to oversee the application of regulatory requirements."

3.141. For a facility in which non-medical human imaging takes place, the radiation protection officer oversees the day to day application of the arrangements for protection and safety, and may provide general radiation protection advice. The radiation protection officer should be granted sufficient authority, resources and organizational freedom to effectively oversee the radiation protection and safety programme and, if required, to stop unsafe activities. There may be a need for more than one radiation protection officer to be appointed by the organization, depending on the extent of their operations.

3.142. The registrant or licensee may also need the services of a qualified expert (see para. 2.46 of GSR Part 3 [1]) to perform various radiation protection measurements and to provide expert advice on particular aspects of protection and safety.

3.143. A qualified expert is defined in GSR Part 3 [1] as an "individual who, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization".

3.144. In the context of non-medical human imaging, the qualified expert would be a person with recognized qualifications and experience in radiation protection and safety or in medical physics. The facility's radiation protection officer may be able to fulfil this role, depending on education, training, qualifications and competence.

Education and training

3.145. GSR Part 3 [1] places great emphasis on education and training for all persons engaged in activities relevant to protection and safety. While it assigns responsibility to the government for establishing requirements in this regard, and to the regulatory body for their application, specific responsibilities are also assigned to registrants and licensees.

3.146. Paragraph 2.44 of GSR Part 3 [1] states:

> "The relevant principal parties [the registrant or licensee of the facility using inspection imaging devices] and other parties having specified responsibilities in relation to protection and safety shall ensure that all personnel engaged in activities relevant to protection and safety have appropriate education, training and qualification so that they understand their responsibilities and can perform their duties competently, with appropriate judgement and in accordance with procedures."

3.147. Paragraph 3.110 of GSR Part 3 [1] requires employers to provide workers with "adequate instruction and training and periodic retraining in protection and safety, and adequate information on the significance of their actions for protection and safety" and to "maintain records of the training provided to individual workers."

3.148. The arrangements for keeping training records should be consistent with regulatory requirements and guidance, and they should be specified in the radiation protection and safety programme.

3.149. The education and training needs of workers in Category 1 and Category 2 practices are considered below.

Category 1 practices

3.150. There are two categories of person to consider with respect to education, training, qualification and competence associated with Category 1 non-medical human imaging practices.

3.151. The first category is those persons involved in applying the selection or eligibility criteria for individuals to undergo Category 1 non-medical human imaging procedures. For example, in the case of drug detection, such persons could include the officers on duty at the border control and persons in the relevant ministry who have the authority to authorize a given procedure. All such persons need an understanding of the following:

(a) The system for regulatory control of the particular Category 1 non-medical human imaging practice;
(b) The conditions of the justification of the practice, including selection criteria and types of examination allowed to be used;

(c) The procedures to be followed for approving an individual Category 1 non-medical human imaging procedure;
(d) The information that should be passed on to the medical radiation facility with regard to the procedure to be performed.

3.152. These persons should also have some understanding of radiation risks and the need to optimize protection and safety to give context to their actions and responsibilities.

3.153. The second category is the medical personnel at the medical radiation facility where the Category 1 non-medical human imaging procedure is to be performed. The education, training, qualifications and competence needed for the use of radiation for medical diagnosis are also sufficient for Category 1 non-medical human imaging procedures. Detailed guidance on these requirements is given in SSG-46 [3]. However, additional training should still be considered, for example, where the imaging protocols for a particular non-medical human imaging procedure are different to the imaging protocol for the corresponding medical procedure.

Category 2 practices

3.154. The radiation protection and safety programme should describe the training programme in protection and safety for all workers directly involved in the management and operation of the Category 2 non-medical human imaging facility. The scope and extent of the training should be commensurate with the role and responsibility of the individual involved. The training should include a radiation 'awareness' programme, where appropriate, for other staff, particularly those working near the inspection zone, such as security guards and administrative staff. Such an awareness programme should be a simplified version of the training provided to operators of inspection imaging devices.

3.155. The radiation protection and safety programme should specify the minimum educational and professional qualifications for relevant staff, especially radiation protection officers and qualified experts, in accordance with regulatory requirements. Specific instruction and training should be provided when new inspection imaging devices and associated equipment and software are introduced. Regular refresher training should also be provided as part of the radiation protection and safety programme, with additional training when inspection imaging devices, software or procedures are changed.

3.156. Specific training should be provided for workers who operate inspection imaging devices. At a minimum, this training should include instruction on pre-operational checks, functional tests, safety features, operation of the system, subject positioning, interpretation of images, procedures to be followed if the system is damaged or malfunctions, and practical operating experience. In addition, workers who operate inspection imaging devices should be given radiation protection and safety training that includes, at a minimum, the following:

(a) The type and properties of the radiation source and the radiation emitted;
(b) The typical radiation exposures from the normal use of the inspection imaging device and from incidents;
(c) The radiation risk for workers and the public, including for persons undergoing non-medical human imaging procedures;
(d) The use of design features, time, distance and shielding to reduce exposures;
(e) Lessons identified from operating experience and from incidents;
(f) Safe working procedures, including procedures for emergency preparedness and response.

Designation of controlled areas and supervised areas

Category 1 practices

3.157. Category 1 non-medical human imaging procedures are carried out in a medical radiation facility. Guidance on the designation of controlled areas and supervised areas in such facilities is provided in SSG-46 [3].

Category 2 practices

3.158. The radiation protection and safety programme should describe where and how controlled areas and supervised areas are to be designated in the Category 2 non-medical human imaging facility, in accordance with the requirements and criteria for designation of areas given in paras 3.88–3.92 of GSR Part 3 [1].

3.159. In accordance with para. 3.88 of GSR Part 3 [1], the designation of controlled areas is required to be based on the need for protection and safety measures to control exposures, and the need to limit the likelihood and magnitude of potential exposures. In practice, for inspection imaging devices, the need to designate controlled areas and supervised areas will be based on the safety assessment and the dose rates to which workers and the public could be exposed, as well as the doses received by persons undergoing imaging procedures.

3.160. Paragraph 3.90(a) of GSR Part 3 [1] requires that controlled areas be delineated by physical means. For some inspection imaging devices, the controlled area is the inspection zone contained within the immediate enclosure. In other cases, the controlled area may be a room set aside for the imaging of persons for the detection of concealed objects for anti-smuggling purposes.

Protection of workers

Category 1 practices

3.161. Category 1 non-medical human imaging procedures will be performed in a medical radiation facility, using medical radiological equipment. The arrangements for occupational radiation protection for performing medical exposures are sufficient to cover Category 1 non-medical human imaging procedures. Detailed guidance on occupational radiation protection in medical radiation facilities is given in section 3 of SSG-46 [3].

Category 2 practices

3.162. In a Category 2 non-medical human imaging facility, occupationally exposed individuals include workers operating inspection imaging devices and performing scans, service engineers, radiation protection officers and qualified experts performing radiation surveys.

3.163. Facility personnel, such as persons controlling entry to the inspection zone or passport control officials, for whom radiation sources are not required by, or directly related to, their work require the same level of protection as members of the public (para. 3.78 of GSR Part 3 [1]). Consequently, the recommendations provided in paras 3.206–3.211 for the protection of the public are also applicable in respect of such workers.

3.164. Comprehensive recommendations on occupational radiation protection, including guidance on radiation protection programmes, are provided in GSG-7 [17].

Local rules and procedures

3.165. Paragraph 3.93 of GSR Part 3 [1] establishes a hierarchy of preventive measures for protection and safety with engineered controls being supported by administrative controls and personal protective equipment. As required in para. 3.94 of GSR Part 3 [1], written local rules and procedures are necessary for

the use of all inspection imaging devices. The purpose of these local rules and procedures is to ensure protection and safety for workers and the public. Local rules that describe the procedures for carrying out non-medical human imaging with inspection imaging devices should be developed and written in a language understood by the people who will need to follow them. These local rules should cover all aspects of operating the inspection imaging devices relevant to protection and safety.

3.166. Management should ensure that all relevant persons have read and understood the local rules. A copy should be provided to all workers that operate the equipment and other relevant persons, and additional copies should be available in the area in which the inspection imaging device is being used.

3.167. The local rules and procedures should include measures to minimize occupational exposure and public exposure during both normal work and in anticipated operational occurrences and accident conditions. The local rules and procedures should describe the arrangements for the wearing, handling and storing of personal dosimeters, if required, and specify investigation levels and follow-up actions, as appropriate (see para. 3.94 of GSR Part 3 [1]).

3.168. Since all workers involved in operating inspection imaging devices in a Category 2 non-medical human imaging facility need to know and follow the local rules and procedures, such workers should also participate in a continual improvement process in which the local rules are reviewed and revised based on operating experience.

3.169. Inspection imaging devices, including both hardware and software, should be operated in a manner that ensures satisfactory performance at all times with respect to the purpose of the imaging procedure and to protection and safety. The operating instructions provided by the manufacturer are an important resource in this respect, but additional procedures are likely to be needed. The registrant or licensee should approve the final set of operating procedures, and the procedures should be documented and incorporated into the registrant's or licensee's management system.

3.170. The registrant or licensee should ensure that workers understand the operating procedures for their work with inspection imaging devices, including the correct use of any safety features, and that such workers have received appropriate training.

3.171. Operational checks of each inspection imaging device should be performed daily based on the manufacturer's recommendations. The registrant or licensee should establish which checks need to be performed, who will perform them and how the results are to be recorded. A qualified expert or radiation protection officer should also be involved in establishing the programme of checks to be undertaken.

Monitoring of the workplace

3.172. Paragraphs 3.96–3.98 of GSR Part 3 [1] set out the requirements and responsibilities for workplace monitoring. Workplace monitoring comprises measurements made in and around inspection imaging devices in operation, and the recording and interpretation of the results. Workplace monitoring can be undertaken for several purposes, including routine monitoring, special monitoring for specific activities or tasks, and confirmatory monitoring to check assumptions made about exposure conditions. The facility's radiation protection officer or qualified expert should provide specific advice on the workplace monitoring programme. Further general guidance on workplace monitoring is given in GSG-7 [17].

3.173. Workplace monitoring can be used to verify the occupational doses of personnel whose work involves exposure to predictable, low levels of radiation. Paragraph 3.101 of GSR Part 3 [1] states:

> "For any worker who regularly works in a supervised area or who enters a controlled area only occasionally, the occupational exposure shall be assessed on the basis of the results of workplace monitoring or individual monitoring, as appropriate."

3.174. The assessment of occupational exposure on the basis of workplace monitoring will generally be appropriate in Category 2 non-medical human imaging facilities.

3.175. Workplace monitoring should be carried out in areas around each inspection imaging device while it is in operation. This monitoring should be carried out:

(a) When the installation has been completed and before the device is first used;
(b) When new software for the inspection imaging device is installed or there is a significant modification or maintenance to the hardware or software;

(c) When servicing that might have an impact on protection and safety has been performed on the inspection imaging device;
(d) If working patterns or other factors change from assumed values.

3.176. The radiation protection and safety programme may include dose or dose rate investigation levels (see para. 3.128 of GSG-7 [17]), set by management, the radiation protection officer or qualified expert, that are the maximum doses or dose rates that are acceptable during the operation of an inspection imaging device, for example at the operator's position and at other specified positions. Such dose and dose rate investigation levels should be consistent with regulatory requirements and guidance. The local rules are required to include any relevant investigation levels and the procedures to be followed in the event that any such level is exceeded (para. 3.94 of GSR Part 3 [1]).

3.177. A programme for the use of workplace monitoring instruments, and by whom, should be specified. The programme should provide information on the recommended frequency of measurements around inspection imaging devices, the details to be recorded and the length of time for which the records should be kept.

3.178. The protection and safety programme should describe the procedures for the selection, calibration, maintenance and testing of workplace monitoring instruments. The instruments used for radiation monitoring should be calibrated in terms of ambient dose equivalent, $H^*(10)$. The frequency of the calibration should be in accordance with regulatory requirements. Records of calibrations should be kept as part of the quality assurance programme.

Assessment of occupational exposure by individual monitoring

3.179. Paragraph 3.100 of GSR Part 3 [1] states:

> "For any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible."

3.180. The purpose of monitoring and dose assessment is to provide information about the actual exposure of workers in order to demonstrate regulatory compliance and to confirm good working practices. Monitoring involves more than just measurement; it also involves interpretation, investigation and reporting, which may lead to corrective measures, if necessary.

3.181. Individual dose monitoring would not normally be expected for a worker in a Category 2 non-medical human imaging facility, but there might be circumstances in which it might be considered. For example, a new facility performing Category 2 non-medical human imaging may decide to perform individual monitoring for an initial period of time to confirm that the inspection imaging devices are functioning as designed and to provide reassurance to the operators in their new role. Periodic individual monitoring may be part of the facility's ongoing quality assurance programme for the inspection imaging devices. As part of the application for an authorization, the registrant or licensee should state whether individual monitoring for occupational exposure is to be carried out.

3.182. The radiation protection and safety programme should specify that the dosimetry service provider should be appropriately approved or accredited. The radiation protection officer or qualified expert should review the dose records periodically to identify doses that may be higher than usual and to review whether doses are as low as reasonably achievable. Detailed guidance can be found in GSG-7 [17].

Investigation levels

3.183. Investigation levels are different to dose constraints and dose limits; they are a tool used by managers to initiate a review of procedures and performance, investigate what is not working as expected and take timely corrective action. More detailed guidance on the purpose and use of investigation levels is provided in GSG-7 [17].

3.184. In a Category 2 non-medical human imaging facility, occupational exposures are expected to be very low, and hence the investigation level should be set at a correspondingly low value, taking into account the sensitivity of the monitoring device and the period of monitoring. For example, for a three month monitoring period, recorded doses higher than 0.25 mSv should be investigated.

3.185. As described in para. 3.176, investigation levels should also be set for workplace monitoring, for example in terms of ambient dose rate. Abnormal conditions or events should also trigger an investigation. In all cases, the investigation should be carried out to improve the implementation of optimization of protection and safety. The investigation should be performed by the registrant or licensee with the assistance of the facility's radiation protection officer and qualified expert, as appropriate. In some cases, the regulatory body may also need to be informed.

3.186. The investigation should be started as soon as possible following the initiating event and a written report should be prepared, which should include details of the cause of the event, the determination or verification of the dose(s) received, any corrective or mitigating actions taken, and instructions or recommendations to avoid a recurrence of the event.

Records of occupational exposure

3.187. Paragraphs 3.103–3.107 of GSR Part 3 [1] state the requirements for records of occupational exposure, placing obligations on the employer, registrant and licensee. As well as demonstrating compliance with legal requirements, records of occupational exposure should be used in assessing the effectiveness of the implementation of optimization of protection and safety, and evaluating trends in exposure. The regulatory body might specify additional requirements for records of occupational exposure and for access to the information contained in those records. Further guidance on records of occupational exposure is given in GSG-7 [17].

Workers' health surveillance

3.188. The primary purpose of health surveillance is to assess the initial and continuing fitness of workers for their intended tasks, and requirements are given in paras 3.108 and 3.109 of GSR Part 3 [1].

3.189. No specific health surveillance related to exposure to ionizing radiation is necessary for workers involved in Category 2 non-medical human imaging procedures. Under normal working conditions, the occupational doses incurred in Category 2 non-medical human imaging procedures are very low and no specific radiation related medical examinations are required for workers.

3.190. If a programme for periodic health surveillance of workers is considered appropriate, it should be provided by a suitable occupational health service under the direction of an occupational physician, as described in section 10 of GSG-7 [17]. As well as routine health surveillance, these arrangements should also be able to provide counselling to workers, including occupationally exposed female workers who suspect that they are pregnant or who may become pregnant, who are concerned about their radiation exposure.

Conditions of service of workers

3.191. Paragraph 3.111 of GSR Part 3 [1] states:

> "The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure. Special compensatory arrangements, or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits, shall neither be granted nor be used as substitutes for measures for protection and safety".

Arrangements for the protection of female workers

3.192. Paragraph 3.113(a) and (b) of GSR Part 3 [1] states:

> "Employers, in cooperation with registrants and licensees, shall provide female workers who are liable to enter controlled areas or supervised areas…with appropriate information on:
>
> (a) The risk to the embryo or fetus due to exposure of a pregnant woman;
> (b) The importance for a female worker of notifying her employer as soon as possible if she suspects that she is pregnant".

3.193. The purpose of notifying the employer is to enable the working conditions for the female worker to be adapted so as to ensure that the embryo or fetus is afforded the same level of protection as a member of the public. This does not mean that it is necessary for pregnant women to avoid work with radiation, but it does imply that the employer should carefully review the working conditions with regard to both normal exposure and potential exposure. In the case of Category 2 non-medical human imaging, there should be no need for any change in the duties of a pregnant operator of an inspection imaging device. However, it is recognized that a pregnant woman may have concerns about working with radiation, even where exposures are very low, and, in addition to the information required to be provided by the employer on the risks to the embryo or fetus, access to individual advice, for example from a qualified expert, should also be made available.

Persons under 18

3.194. Paragraph 3.115 of GSR Part 3 [1] requires that "no person under the age of 16 years is or could be subject to occupational exposure." While probably

unlikely, a trainee operator aged 16 to 18 years could commence training under supervision to become an operator of an inspection device. Paragraph 3.116 of GSR Part 3 [1] states the requirements for access to controlled areas, and the dose limits for such persons are more restrictive. Box 1 in the Appendix to this Safety Guide reproduces the dose limits from Schedule III of GSR Part 3 [1], including those for apprentices of 16 to 18 years of age.

Protection of persons undergoing non-medical human imaging

3.195. Procedures should be established for determining who is, and who is not, to undergo a non-medical human imaging procedure. The authorization, on the basis of the justification process, should specify any general conditions and restrictions in terms of the persons to undergo such procedures, but local procedures should also be established. For some Category 2 practices, it may be the case that every person, for example passing through a security zone, is to be imaged. For other practices, it may be on the basis of a random selection of persons, or the specific selection of individuals based on intelligence by law enforcement agencies. The approach to the selection of children and pregnant women for imaging procedures should be considered in these procedures.

Category 1 practices

3.196. Category 1 non-medical human imaging procedures will be performed in a medical radiation facility, using medical radiological equipment. The arrangements for protection of patients undergoing diagnostic medical exposures will largely be sufficient to cover Category 1 non-medical human imaging procedures, but with the additional requirement to use appropriate imaging protocols for the non-medical human imaging procedures. Detailed guidance on the optimization of radiation protection for persons undergoing medical exposures is given in section 3 of SSG -46 [3].

Category 2 practices

3.197. Paragraph 3.65 of GSR Part 3 [1] states:

> "Procedures with inspection imaging devices in which radiation is used to expose persons for the purpose of detection of concealed weapons, contraband or other objects on or within the body shall be considered to give rise to public exposure."

As such, the requirements for public exposure in planned situations in GSR Part 3 [1] need to be applied for the protection of persons undergoing Category 2 non-medical human imaging procedures. Paragraphs 3.198–3.204 specifically cover the application of these requirements.

3.198. There may be situations in which workers undergo Category 2 non-medical human imaging, for example air crew and airport staff who are required to undergo the same security screening as passengers. This is not to be considered occupational exposure: as stated in para. 3.65 of GSR Part 3 [1], such exposure is to be considered public exposure.

3.199. The operator of the inspection imaging device should ensure that only the person intended to be imaged is within the inspection zone, and that the person is positioned correctly, before initiating the exposure.

3.200. The radiation protection and safety programme should describe the procedure for periodically determining the doses to persons undergoing Category 2 non-medical human imaging. This procedure should describe the measurement methodology and frequency, and the persons that will carry out the measurements. The ANSI standard on radiation safety for personnel security screening systems provides a measurement methodology and recommends a frequency of at least once every 12 months to establish the reference effective dose per screening for each type of imaging procedure [38]. From this, the annual dose can be estimated by multiplying the reference effective dose per screening by the estimated number of screenings to an individual in a year. The estimated annual dose should be consistent with regulatory requirements and guidance, and in particular should comply with the dose constraint set by the government or regulatory body (see paras 3.11–3.14). The radiation protection officer or qualified expert should review the reference effective dose per screening to identify those that may be higher than usual and to review whether doses are as low as reasonably achievable.

3.201. Paragraph 3.66 of GSR Part 3 [1] states:

> "Registrants and licensees shall ensure that all persons who are to undergo procedures with inspection imaging devices in which ionizing radiation is used are informed of the possibility of requesting the use of an alternative inspection technique that does not use ionizing radiation, where available."

Consequently, where an alternative inspection technique exists, procedures should be established to provide the above information.

3.202. In addition, procedures should be established to deal with requests for additional information from persons who have concerns about undergoing a non-medical imaging procedure. It is recommended that the registrant or licensee designate personnel with appropriate knowledge and training to handle these requests.

3.203. The role of dose constraints for public exposure in relation to Category 2 non-medical human imaging procedures is described in paras 3.12–3.14. In many cases, a person might undergo only one or two Category 2 non-medical human imaging procedures in a year, while other persons could undergo a much larger number of procedures. The dose constraint should be established in terms of the cumulative individual effective dose for the year and should apply to all persons. Depending on the particular authorized practice, this may require a very low effective dose per imaging procedure. For example, in a general use practice, where the number of procedures a person could undergo in a year is not controlled and is potentially quite high, the reference effective dose per image would need to be very low and less than 0.1 μSv. A limited use practice will produce a higher effective dose per screening and there should be arrangements in place to control the number of imaging procedures a person undergoes. In some cases, there might even be a need to estimate and record the cumulative dose received by certain individuals.

Provision of information

3.204. Procedures should be established to ensure that each individual to be imaged is provided with information about the imaging process. The licensee should ensure that such information is pre-prepared and available. The level of information provided should be commensurate with the risk of the imaging process. There are many possible methods for providing the information and the best method will depend on the person being imaged and the situation. Brochures, fact sheets, 'question and answer' sheets and posters may be appropriate when there are large numbers of individuals passing through the system. Briefings and video clips may be appropriate for situations in which there are a limited number of individuals being routinely screened. Consideration should be given to providing the information in several languages that are commonly encountered at the facility where the non-medical imaging is being carried out. At a minimum, the information should include the following:

(a) A statement that the inspection imaging device emits ionizing radiation;

(b) The effective dose to a person from a single scan and the number of scans that would be necessary to produce an effective dose equal to the public dose constraint;
(c) Comparisons of the effective dose from the imaging procedure to other common sources of exposure, such as natural background radiation;
(d) A description of the alternative inspection technique that does not use ionizing radiation, where available;
(e) A confirmation that the practice complies with regulatory requirements.

Protection of the public

Category 1 practices

3.205. Justified Category 1 non-medical human imaging procedures will be performed in a medical radiation facility, using medical radiological equipment. Arrangements to ensure the protection and safety of the public with respect to medical radiation facilities are also sufficient to cover Category 1 non-medical human imaging procedures. Detailed guidance on radiation protection of the public is given in section 3 of SSG-46 [3].

Category 2 practices

3.206. The radiation protection and safety programme should describe the procedure for periodically estimating the likely doses to members of the public arising from the Category 2 non-medical human imaging practice. The procedure should include the methodology by which public exposure is estimated, how often this is undertaken and by whom. The radiation protection officer or qualified expert should review the estimated doses to determine whether doses to the public are as low as reasonably achievable.

3.207. Paragraphs 3.117–3.129 and 3.135–3.137 of GSR Part 3 [1] set out the requirements for the protection of the public that are relevant to the use of inspection imaging devices in Category 2 non-medical human imaging facilities. General guidance on protection of the public can be found in GSG-8 [15].

3.208. The primary means for protecting members of the public (and also facility personnel for whom radiation sources are not directly related to their work; see para. 3.163) is to ensure that the shielding integral to the inspection imaging devices is sufficient to ensure that the exposure from being in any accessible adjacent area, including rooms above and below, is in compliance with

the public dose limits and below any dose constraint that the regulatory body may have established or approved (see paras 1.23 and 3.120 of GSR Part 3 [1]).

Control of access

3.209. In addition to providing adequate shielding, the registrant or licensee should ensure that access by members of the public (and by facility personnel for whom radiation sources are not directly related to their work: see para. 3.163) to the area where non-medical human imaging is undertaken is controlled. The registrant or licensee should put arrangements in place to ensure that the only persons who enter the inspection zone are those who have been selected for a Category 2 non-medical human imaging procedure and that such persons have been informed to this effect. To facilitate the control of access, there should be a limited number of entry paths into the inspection zone, with access being controlled by facility personnel. In addition, there should be signs placed at the entry points to the inspection zone stating clearly who is permitted to enter this zone.

Monitoring and reporting

3.210. Paragraph 3.137 of GSR Part 3 [1] sets out the requirements to be met by the registrants or licensees of a Category 2 non-medical human imaging facility with respect to monitoring and reporting of public exposure. Procedures should be in place to ensure that:

(a) A monitoring programme for public exposure is established and implemented;
(b) Appropriate records of the results of the monitoring programme are kept and made available on request.

3.211. The programme for monitoring public exposure arising from the use of inspection imaging devices should include an assessment of the doses to persons in areas that are accessible to members of the public. Such an assessment is likely to have been part of the shielding calculations undertaken at the design stage: this should be reviewed and combined with workplace monitoring results from the initial operation of the device and periodically thereafter.

Safety of equipment used for non-medical human imaging

Category 1 practices

3.212. Category 1 non-medical human imaging procedures will be performed in a medical radiation facility, using medical radiological equipment. The radiation protection and safety requirements for these facilities and equipment for performing medical exposures are sufficient to cover Category 1 non-medical human imaging procedures. Detailed guidance on the safety of medical radiation facilities and medical radiological equipment is given in SSG-46 [3].

Category 2 practices: Safety assessment

3.213. In the context of Category 2 non-medical human imaging, a safety assessment means an assessment of all aspects of radiation protection and safety that are relevant to a Category 2 non-medical human imaging facility, including the siting, design and operation of the facility.

3.214. The regulatory body has a responsibility to establish requirements for safety assessment and to review and assess the safety assessment prior to granting an authorization (see Requirement 13 and para. 3.29 of GSR Part 3 [1]). The applicant for an authorization, or the registrant or licensee (see para. 3.30 of GSR Part 3 [1]), is responsible for preparing the safety assessment. Safety assessments are required to be conducted at different stages, as appropriate, including before a Category 2 non-medical human imaging facility is operational and when a major change in operation is contemplated (see para. 3.31 of GSR Part 3 [1]).

3.215. Paragraphs 3.30–3.36 of GSR Part 3 [1] provide requirements on the content of a safety assessment, the factors that the registrant or licensee is required to take into account when preparing the safety assessment, the documentation and placement of the safety assessment in the management system, and when additional reviews of the safety assessment need to take place. More detailed requirements on safety assessment for facilities and activities are given in GSR Part 4 (Rev. 1) [30]. For Category 2 non-medical human imaging procedures, the safety assessment should include not only considerations of occupational and public exposure and the exposure of persons being imaged, but also the possibility of accidental exposures.

3.216. GSR Part 3 [1] specifies two types of safety assessment — generic or specific to the practice or source. As stated in footnote 29, para. 3.30 of GSR Part 3 [1]:

> "A generic safety assessment is usually sufficient for types of source with a high degree of uniformity in design. A specific safety assessment is usually required in other cases; however, the specific safety assessment need not include those aspects covered by a generic safety assessment, if a generic safety assessment has been conducted for the type of source."

3.217. The safety assessments needed in the context of Category 2 non-medical human imaging will range in complexity, but even if an inspection imaging device is covered by a generic safety assessment, its placement and use in a Category 2 non-medical human imaging facility will nearly always need to be considered in some form of specific safety assessment.

3.218. The safety assessment should provide a basis for decision making in relation to the following:

(a) The engineered control measures that are required for safety;
(b) The development of local rules and procedures to be followed by workers operating Category 2 non-medical human imaging equipment;
(c) Requirements and procedures for designating controlled areas and supervised areas;
(d) Any requirements for protection of persons undergoing imaging procedures;
(e) Any requirements for protection of workers and the public;
(f) The measures required to minimize the likelihood of incidents occurring and consequences if events occur.

Prevention of accidents

3.219. Accident prevention is the best means for avoiding accidental exposure, and paras 3.39–3.42 of GSR Part 3 [1] set out requirements for good engineering practice, defence in depth and accident prevention. Design considerations for Category 2 non-medical human imaging facilities are described in paras 3.222–3.225.

3.220. For Category 2 non-medical human imaging procedures, possible scenarios for accidental exposure include flaws in the design of inspection imaging devices, failures of engineered controls on such devices while in operation, failures and errors in the software that control or influence the

emission of radiation from the inspection imaging device, and human error. Another scenario for potential public exposure is inadvertent entry of persons into the inspection zone. Control of access to the inspection zone is addressed in para. 3.209.

Design of equipment

3.221. Paragraph 3.67 of GSR Part 3 [1] states:

> "The registrant or licensee shall ensure that any inspection imaging device used for the detection of concealed objects on or within the body, whether it is manufactured in or imported into the State in which it is used, conforms to applicable standards of the International Electrotechnical Commission or the International Organization for Standardization or to equivalent national standards."

Relevant design standards for inspection imaging devices for Category 2 non-medical human imaging are described in para. 3.51, and general design considerations for safety are given in para. 3.52.

Design of the facility

3.222. Paragraph 3.51 of GSR Part 3 [1] sets out the general safety requirements that need to be met when choosing a location for performing Category 2 non-medical human imaging. Provisions for the incorporation of safety features are best made during the design stage of the facility. The siting and layout of the facility should take into account the occupancy of adjacent areas, doses per scan, workload, system orientation (i.e. beam direction) and the flow of people.

3.223. The design of a Category 2 non-medical human imaging device should be such that it incorporates all the necessary shielding to ensure that occupational exposure and public exposure arising from its use will be well below the relevant dose limits and will meet the applicable dose constraints. Consequently, it would not be expected to need additional structural shielding for the facility.

3.224. During the design stage, the area of the inspection zone should be determined, documented and clearly indicated.

3.225. Signs and warning lights, preferably positioned at eye level, should be positioned at the entrances of any controlled areas and supervised areas, as appropriate, to prevent inadvertent entry (see also para. 3.209 on control

of access). For controlled areas, para. 3.90(c) of GSR Part 3 [1] requires that registrants and licensees display the basic ionizing radiation symbol recommended by the International Organization for Standardization [21] at entrance points and at appropriate locations within the controlled area. All signs should be clear and easily understandable. Warning signals, such as illuminated or flashing lights or signs, should be activated when radiation is being produced.

Installation, commissioning, testing and maintenance of inspection imaging devices

3.226. Paragraphs 3.15(i) and 3.41 of GSR Part 3 [1] include requirements for maintenance and testing to ensure that inspection imaging devices meet their design requirements for protection and safety throughout their lifetime and to prevent accidents as far as reasonably practicable.

3.227. Inspection imaging devices should be installed in accordance with the manufacturer's instructions and the installation should comply with relevant regulatory requirements and authorization conditions. As noted in para. 3.33, only properly trained and authorized individuals should be allowed to install inspection imaging devices.

3.228. Acceptance tests should be performed for new or modified or repaired devices, or after the installation of new software or the modification of existing software that could affect protection and safety. Depending on the agreement between the manufacturer or supplier and the end user, acceptance tests can be performed by the manufacturer's representative in the presence of the radiation protection officer or qualified expert representing the licensee or registrant, or by a radiation protection officer or qualified expert jointly with the manufacturer's representative. Whatever the case, the arrangements should be agreed in advance and it should be ensured that the process involves the verification of all specifications and features of the device relevant to protection and safety.

3.229. After satisfactory completion of the acceptance tests and before the inspection imaging device is put into use, commissioning tests should be carried out by, or under the supervision of, the radiation protection officer or qualified expert. Commissioning should include measurements of all parameters and conditions of use that are expected in operation. For many inspection imaging devices, there may be little difference between acceptance tests and commissioning. As part of the commissioning, the baseline for subsequent constancy tests (e.g. to determine the dose from a single scan) should be established. The registrant or licensee should ensure that the performance of the

inspection imaging device meets regulatory requirements and any conditions of the authorization. In addition, a qualified expert should perform a radiation survey of the inspection imaging device and, if applicable, the inspection facility to verify that protection and safety are optimized.

3.230. After installation of inspection imaging devices or software, the supplier should conduct a formal handover to the registrant or licensee. This handover should include testing to verify that the inspection imaging device and software are performing to the required standards (see para. 3.49(a) of GSR Part 3 [1]) and specific training in the use of the device and software for the workers involved in operating the device. The features of the device and software should be fully understood, including their implications for protection and safety. A written report by the installation engineer detailing the post-installation performance results should be provided to the licensee before the device is put into use.

3.231. The registrant or licensee should ensure that adequate maintenance (preventive and corrective) is performed as necessary to ensure that inspection imaging devices retain, or improve through appropriate hardware and/or software upgrades, their design specifications for protection and safety for their full lifetime. The registrant or licensee should, therefore, establish the necessary arrangements and coordination with the manufacturer's representative and/or installer before initial operation and on an ongoing basis thereafter.

3.232. Maintenance procedures should be carried out at the frequency recommended by the manufacturer of the device. Maintenance records should be kept for each device: these records should include information on any defects found by users (a fault log), remedial actions taken (both interim and subsequent repairs) and the results of testing before a device is reintroduced into use.

Quality assurance programme

3.233. A quality assurance programme for the use of inspection imaging devices should be established and should include documentation, radiation monitoring, quality control tests, training, records, a preventive maintenance programme, and a review of local rules and procedures. The quality assurance programme should be designed to ensure that all equipment and safety systems are regularly subjected to quality control tests, and that any faults or deficiencies are brought to the attention of the management and are promptly remedied. The purpose of the quality control tests is to ensure that, at all times, all inspection imaging devices are performing correctly, accurately, reproducibly and predictably. The

quality control programme should include the establishment of a baseline set of measurements to be taken at the acceptance testing stage (see para. 3.228).

3.234. The regulatory body may have its own specific requirements on the quality control tests that need to be performed and their frequencies.

3.235. The regulatory body should review the records of the quality assurance programme during inspections of facilities and activities using inspection imaging devices.

Periodic reviews and audits of the performance of the radiation protection and safety programme

3.236. As an integral part of the registrant's or licensee's management system, the radiation protection and safety programme, and its implementation should be reviewed on a regular basis. This periodic review should identify any problems that need to be addressed and any modifications that could improve the effectiveness of the radiation protection and safety programme.

3.237. Factors to be considered include the selection and qualification of the persons who will conduct the internal reviews, the frequency of reviews, the expectations of the review team, the procedures for reporting of results and their follow-up.

3.238. A key part of this periodic review process is a routine series of audits. Factors to be considered include the selection and qualification of the persons who will conduct the audits, the frequency of audits, the expectations of the audit team, the procedures for reporting of results and their follow-up.

Records

3.239. Records are an important part of demonstrating ongoing compliance with radiation protection requirements.

Category 1 practices

3.240. For a medical radiation facility carrying out Category 1 non-medical human imaging procedures, the records kept should include the number of individuals undergoing such procedures each year and the protocols for each type of procedure being carried out in the medical radiation facility.

Category 2 practices

3.241. For a Category 2 non-medical human imaging facility, the records kept should include:

(a) Use and maintenance logs: Records of upgrades, modifications, maintenance and repair should be maintained for the life of the inspection imaging devices (paras 3.226–3.232).
(b) Quality assurance programme records: Records of all aspects of the quality assurance programme, including acceptance tests (paras 3.233–3.235).
(c) Training records: Records of all training, including the date of training, an outline of the training and the names of those in attendance (paras 3.145–3.156).
(d) Radiation monitoring: Records of individual monitoring and workplace monitoring, and reports of any investigations (paras 3.172–3.182).
(e) Doses to persons that have undergone imaging procedures: Records of the reference effective dose per screening for each inspection imaging device in use. In the case of limited use systems for individuals who could receive radiation doses approaching the dose constraint, such as employees or frequent visitors, records should be maintained that include the number of times that the individual was scanned and the cumulative effective dose to the individual in any year.
(f) Events: Records of any events, including corrective actions (paras 3.242–3.244).

The records should be kept for the period specified by the regulatory body.

INVESTIGATION OF EVENTS

3.242. All relevant staff should be adequately trained to be able to recognize when an inspection imaging device might not be functioning correctly, either due to hardware or software problems and, when necessary, to immediately terminate an imaging procedure.

3.243. If an event that is significant for protection and safety occurs, the registrant or licensee should conduct an investigation, the aim of which is:

(a) To determine the root cause of the event;
(b) To estimate the doses received by the exposed persons (i.e. workers, imaged persons and members of the public), as applicable;

(c) To ensure that any exposed persons are informed about the accidental exposure;
(d) To identify and implement any corrective actions necessary to prevent the recurrence of such an event;
(e) To implement all of the corrective actions that are the responsibility of the licensee.

3.244. The registrant or licensee should produce a written record that contains the information specified above, as relevant, and any other information required by the regulatory body. This should be done as soon as possible after the investigation or as otherwise required by the regulatory body. For significant accidental exposures, or as otherwise required by the regulatory body, this written record should be submitted to the regulatory body as soon as possible. A copy should be kept by the registrant or licensee.

APPENDIX

BOX 1: DOSE LIMITS FOR PLANNED EXPOSURE SITUATIONS

OCCUPATIONAL EXPOSURE

III.1. For occupational exposure of workers over the age of 18 years, the dose limits are:

(a) An effective dose of 20 mSv per year averaged over five consecutive years[66] (100 mSv in 5 years) and of 50 mSv in any single year;
(b) An equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;
(c) An equivalent dose to the extremities (hands and feet) or to the skin[67] of 500 mSv in a year.

Additional restrictions apply to occupational exposure for a female worker who has notified pregnancy or is breast-feeding (para. 3.114 of [GSR Part 3]).

III.2. For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are:

(a) An effective dose of 6 mSv in a year;
(b) An equivalent dose to the lens of the eye of 20 mSv in a year;
(c) An equivalent dose to the extremities (hands and feet) or to the skin[67] of 150 mSv in a year.

PUBLIC EXPOSURE

III.3. For public exposure, the dose limits are:

(a) An effective dose of 1 mSv in a year;
(b) In special circumstances[68], a higher value of effective dose in a single year could apply, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year;
(c) An equivalent dose to the lens of the eye of 15 mSv in a year;
(d) An equivalent dose to the skin of 50 mSv in a year.

Source: Schedule III of GSR Part 3 [1].

[66] The start of the averaging period shall be coincident with the first day of the relevant annual period after the date of entry into force of these Standards, with no retrospective averaging.

[67] The equivalent dose limits for the skin apply to the average dose over 1 cm^2 of the most highly irradiated area of the skin. The dose to the skin also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.

[68] For example, in authorized, justified and planned operational conditions that lead to transitory increases in exposures.

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