

International Training Course on the IAEA Safety Standards at Tokai University, 11-14 March 2024 GSR Part 3 Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

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Fundamental Safety Objective



The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation.

IAEA Safety Standards

for protecting people and the environment

Fundamental Safety Principles

Luratom FAO IAEA ILO IMO OECDINEA PAHO UNEP WHO

Safety Fundamentals No. SF-1



Principle 4: Justification of facilities and activities

Facilities and activities that give rise to radiation risks must yield an overall benefit.

Principle 5: Optimization of protection

Protection must be optimized to provide the highest level of safety that can reasonably be achieved.

Principle 6: Limitation of risks to individuals

Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.

Principle 10: Justification and optimization of protective actions to reduce existing or unregulated radiation risks

Relationship of radiation doses and health effects







What do we know at low doses?





Source: UNSCEAR, 2012 Report – Sources, effects and risks of ionizing Radiation, Annex A, p. 27

- "The doses in the figure are in addition to the total background exposure to natural sources of radiation.
- The data points and confidence intervals marked on the graph represent observations of increased frequency of occurrence of a specific cancer type in populations exposed to moderate doses.
- The various lines represent the following plausible dose-response relationships for inferred risk of cancer for exposures in the ranges of low and very low doses:

(a) supralinear;

(b) linear nonthreshold (LNT);

(c) linear–quadratic;

(d) threshold; and

(e) hormetic."

The LNT dose-response relationship is assumed for the purposes of radiation protection



<u>Linear-non-threshold (LNT) model</u>: dose-response model which is based on the assumption that, in the low dose range, radiation doses greater than zero will increase the risk of excess cancer and/or heritable disease in a simple proportionate manner.



ICRP Publication 103, 2007

The practical system of radiological protection recommended by the Commission will continue to be based upon the assumption that at doses below about 100 mSv a given increment in dose will produce a directly proportionate increment in the probability of incurring cancer or heritable effects attributable to radiation.

The Commission considers that the adoption of the LNT model combined with a judged value of a dose and dose rate effectiveness factor (DDREF) provides a prudent basis for the practical purposes of radiological protection, i.e., the management of risks from low-dose radiation exposure.

The UNSCEAR



UN Scientific Committee on the Effects of Atomic Radiation *established in 1955*

OURCES AND EFFECTS

(1)

Mandate:

- to report on the exposure of people to radiation worldwide
- to assess the scientific information on the effects of exposure to ionizing radiation.

Reports: sources of authoritative information

How much radiation is there?

How dangerous is it?

Governments and organizations throughout the world rely on UNSCEAR's estimates as the scientific basis for evaluating radiation risk and for establishing protective measures.



Scientists from 27 countries

The ICRP



An independent, international organisation that advances for the public benefit the science of radiological protection, in particular by providing recommendations and guidance on all aspects of protection against ionising radiation

A community of more than 250 globally-recognised experts in radiological protection science, policy, and practice from more than 30 countries





Evolution of BSS and ICRP Recommendations





Inter-Agency Committee on Radiation Safety

The IACRS Main Achievement

- Through the IACRS, relevant international organizations and bodies contribute significantly to the evolution of the scientific and legal framework in the field of radiation protection and towards international harmonization of radiation protection and safety.
- The IACRS played a key role in the development of the International Basic Safety Standards (BSS) in 1996, last revised in 2011 and published in 2014.



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Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

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General Safety Requirements Part 3 No. GSR Part 3



IAEA Safety Standards



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Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

General Safety Requirements Part 3 No. GSR Part 3





The 3 pillars of the system of radiological protection





Lauriston S. Tylor Chair of ICRP 1937-1962

"Radiation protection is not only a matter for science. It is a problem of philosophy, and morality, and the utmost wisdom"

The Philosophy Underlying Radiation Protection Am. J. Roent. Vol. 77, N° 5, 914 -919, 1957 from address on 7 Nov. 1956

Framework for Applying Radiation Protection Principles



The system of radiological protection – Rule of three

System of radiological protection

"Radiation protection is not only a matter for science. It is a problem of philosophy, and morality, and the utmost wisdom" L.S. Tylor, Chair of ICRP 1937-62

3 Exposure Situations

Planned exposure situations

Emergency exposure situations

Existing exposure situations

Situations involving the planned introduction and operation of sources (including decommissioning, disposal of radioactive waste, rehabilitation)

Unexpected situations such as those that may occur during of a planned situation, or from a malicious act, requiring urgent attention Situations that already exist when a decision on control has to be taken, such as those by natural background radiation and residues from past practices operated outside the system

3 Categories of Exposure

Public exposure

Occupational exposure

Medical exposure

"Public exposures encompasses all exposures of the public other than occupational exposure and medical exposures of patients." ICRP 103, §180

"Exposure incurred by members of the public due to sources in planned exposure situations, emergency exposure situations and existing exposure situations, excluding any occupational exposure or medical exposure." GSR Part 3

"... radiation exposures incurred at work as a result of (exposure) situations that can reasonably be regarded as being the responsibility of the operating management." ICRP 103, §17

Exposure of workers incurred in the course of their work <u>GSR Part 3</u>

"Radiation exposures of patients occur in diagnostic, interventional, and therapeutic procedures."

ICRP 103, §181

See also: Definitions in GSR Part 3

3 Basic Radiation Protection Principles

Any decision that alters the radiation exposure situation should do more good than harm The likelihood of incurring exposure, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors (ALARA)

The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the specified dose limits

GSR Part 3 overall structure

- Section 1: Introduction
- Section 2: General Requirements for Protection and Safety (Requirements 1-5)
- Section 3: Planned Exposure Situations
 - Generic requirements (Requirements 6-18)
 - Occupational Exposure (Requirements 19-28)
 - Public Exposure (Requirements 29-33)
 - Medical Exposure (Requirements 34-42)
- Section 4: Emergency Exposure Situations (Requirements 43-46)
- Section 5: Existing Exposure Situations (Requirements 47-52)
- Schedules (I-IV)
- Annex
- Definitions

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General Safety Requirements Part 3 No. GSR Part 3

Total of 52 requirements

General requirements

Section 2: General Requirements for Protection and Safety

Requirement 1: Application of the principles of radiation protection

Requirement 2: Establishment of a legal and regulatory framework

Requirement 3: Responsibilities of the regulatory body

Requirement 4: Responsibilities for Protection and Safety

Requirement 5: Management for Protection and Safety

All parties: application of principles of Radiation Protection: justification, optimization, limitation and use of a graded approach

Governments: establishment of legal and regulatory framework; efficient and independent regulatory body

Authorities: establishment/adoption of regulations and ensure implementation

The person or organization responsible for facilities and activities that give rise to radiation risks shall have the prime responsibility for protection and safety.

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

PLANNED EXPOSURE SITUATIONS Generic requirements

Planned exposure situations

Section 3: Requirements 6-42

Situations involving the planned introduction and operation of sources to enable regulatory control and radiation protection measures to be provided from the start of activities.

Requirement 6: Graded approach

The application of the requirements of these Standards in **planned exposure situations** shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures.

Requirement 7: Notification and authorization

Any person or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body a notification and, as appropriate, an application for authorization.

Concerns following activities:

3.5. No person or organization shall *adopt, introduce, conduct, discontinue or cease a practice*, or shall, as applicable, *mine, extract, process, design, manufacture, construct, assemble, install, acquire, import, export, supply, provide, distribute, loan, hire, receive, site, locate, commission, possess, use, operate, maintain, repair, transfer, decommission, disassemble, transport, store or dispose of a source* within a practice other than in accordance with the requirements of these Standards.

Notification

- The likelihood and magnitude of potential exposures are negligible
- Required for consumer products only with respect to manufacture, maintenance, import, export, provision, distribution and in some cases disposal.

Authorization

- Registration or licensing
- When notification alone is not sufficient
- Assessment for radiological environmental impacts commensurate with the radiation risks associated with the facility or activity

Requirement 8: Exemption and clearance

Sources or practices, with **low radiation risk**, or no benefit from regulatory control can be exempted from some or all the BSS requirements.

The determination by a regulatory body that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure and the potential exposure due to the source or practice are too small to warrant the application of those aspects or that this is the optimum option for protection irrespective of the actual level of the doses or risks.

CLEARANCE

Materials, with **low radiation risk**, or no benefit from further regulatory control can be cleared from all requirements of the BSS

The removal of regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized practices

Requirement 8: Exemption and clearance

Requirement 9: Responsibilities of registrants and licensees in planned exposure situations

Registrants and licensees shall be responsible for protection and safety in planned exposure situations.

Registrants and licensees bear the responsibility for setting up and implementing the technical and organizational measures that are necessary for protection and safety

- They may designate suitably qualified persons to carry out tasks relating to these responsibilities, but <u>they shall retain the prime</u> <u>responsibility for protection and safety</u>
- Regulatory body shall be notified of any intention to introduce modifications to any practice or source for which they are authorized, whenever the modifications could have significant implications for protection and Safety. <u>Such modification shall not</u> <u>be carried out unless it is specifically authorized by the regulatory</u> <u>body.</u>
- Other responsibilities of registrants include *inter alia* establishment of clear lines of responsibility and accountability for the protection and safety for the sources, conduct of safety assessment, radiological environmental impacts assessment etc.

Requirement 10: Justification of practices

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

<u>Justification:</u> the process of determining whether a practice is, overall, beneficial, i.e., whether the expected benefits from introducing the practice outweigh the harm

In many cases, decisions relating to benefit and risk are taken at the highest levels of government, such as a decision by a State to embark on a nuclear power programme. (SF-1, para 3.19)

NOT justified:

- > Deliberate addition of radionuclides (or activation) in food
- × "Frivolous uses" (toys, jewellery)
- × Human imaging for art, publicity or theft detection

Only justified in expectional circumstances

- Human imaging for occupational, legal or insurance reasons
- Human imaging for concealed objects (smuggling, criminal acts/national security threat)

See also: IAEA Safety Standards Series No. GSG-5, Justification of Practices, Including Non-Medical Human Imaging

Requirement 11: Optimization of Protection and Safety

The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized

<u>Optimization:</u> the process of determining what level of protection and safety would result in individual doses, the number of exposed and the likelihood of exposure being "as low as reasonably achievable, economic and social factors being taken into account" (ALARA). Optimization is an iterative process that involves:

Evaluation of exposure situation

Selection of appropriate value for the dose constraint

Identification and quantification of possible protection options

Selection of the best option under prevailing circumstances

Does not imply minimization or elimination of risk

Implementation of the selected option

Dose constraint

A prospective and source related value of individual dose that is used as a parameter for the optimization of protection and safety for the source, and that serves as a boundary in defining the range of options in optimization

Factors to consider in setting dose constraint:

The characteristics of the source and the practice

Good practice in the operation of similar sources

Dose contributions from other authorized practices

The views of interested parties

Licensees are required to use constraints in the process of optimization

Dose limit

Optimized level

Requirement 12: Dose limits

The government or the regulatory body shall establish dose limits for occupational exposure and public exposure, and registrants and licensees shall apply these limits.

	Occupational Dose Limits	Public Dose Limits
Effective dose (whole body)	20 mSv/year, averaged over 5 years and not exceeding 50 mSv in any single year	1 mSv/year, or exceptionally more in a 1 year provided that the 5 year average does not exceed 1 mSv/year
Equivalent dose (lens of the eye)	20 mSv/year, averaged over 5 years (and 50 mSv/year)	15 mSv/year
Equivalent dose (skin)	500 mSv/year	50 mSv/year
Equivalent dose (hands and feet)	500 mSv/year	-

See: GSR Part 3, Schedule III

Concepts of dose limit and dose constraint

Dose constraints and reference levels

Bands of Projected Dose (mSv)	Radiological Protection Requirements	Examples
20 to 100	Individuals exposed by sources that are not controllable or where actions to reduce doses would be highly disruptive. Benefit on a case-by-case basis. Information, training and individual monitoring of workers, assessment of public doses.	Constraint for evacuation in a radiological emergency.
1 to 20	Individual direct or indirect benefit. Information, training and either individual monitoring or assessment.	Constraints for occupational exposure in planned situations. Dose constraint for radon in dwellings.
under 1	Societal benefit (not individual). No information, training or individual monitoring. Assessment of doses for compliance.	Constraints set for public exposure in planned situations.

Requirement 13: Safety assessment Requirement 14: Monitoring for verification of compliance

The regulatory body shall establish and enforce requirements for safety assessment, and the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of this facility or activity.

<u>The safety assessment consists of a systematic</u> <u>critical review of:</u>

- Ways in which exposure could be incurred
- Effects of external events
- Expected likelihood and magnitudes of exposures in normal operation
- Potential exposures from accidents, and
- Adequacy of the provisions for Protection and safety

See more in GSR Part 3 paras. 3.29-3.36 and in GSR Part 4

IAEA Safety Standards for protecting people and the environment

Safety Assessment for Facilities and Activities

General Safety Requirements No. GSR Part 4 (Rev. 1)

<u>Requirement 14</u>: Registrants and licensees and employers shall conduct monitoring to verify compliance with the requirements for protection and safety.

Requirement 15: Prevention and mitigation of accidents

Registrants and licensees shall apply good engineering practice and shall take all practicable measures to prevent accidents and to mitigate the consequences of those accidents that do occur.

The siting, location, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities or parts thereof **are based on good engineering practice**.

Structures, systems and components, that are related to protection and safety for facilities and activities **are designed**, **constructed**, **commissioned**, **operated and maintained so as to prevent accidents** as far as reasonably practicable.

- Preventing accidents
- Mitigating the consequences of any accident that do occur
- **Restoring** the sources to safe conditions after any such accidents

Emergency plan:

- Provision for individual monitoring and area monitoring, and arrangements for medical treatment;
- Arrangements for assessing and mitigating any consequences of an emergency.
Requirement 16: Investigations and feedback of information on operating experience



Registrants and licensees shall conduct formal investigations of abnormal conditions arising in the operation of facilities or the conduct of activities, and shall disseminate information that is significant for protection and safety.

An investigation shall be conducted in the event that:

A quantity or operating parameter relating to protection and safety exceeds an investigation level or is outside the stipulated range of operating conditions Any equipment failure, accident, error, mishap or other unusual event or condition occurs that has the potential for causing a quantity to exceed any relevant limit or operating restriction.

Requirement 17: Radiation generators and radioactive sources



Registrants and licensees shall ensure the safety of radiation generators and radioactive sources.



Requirement 18: Human imaging using radiation for purposes other than medical diagnosis, medical treatment or IAE biomedical research

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.

Examples for human imagining using radiation:

- Assessment of fitness for employment
- Assessment of athletes, physiological suitability for a sport etc.
- Determination of age for legal purposes
- Obtaining evidence for legal purposes
- Detection of drugs concealed within the body
- Immigration or emigration requirements
- Pre-insurance checks
- Obtaining evidence for the purposes of a compensation claim



The government shall ensure proper justification of such practices (see para. 3.61 of GSR Part 3)

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

IAEA Safety Standards

Specific Safety Guide No. SSG-55

(A) IAEA

IAEA Safety Standards for protecting people and the environment

Justification of Practices, Including Non-Medical Human Imaging

General Safety Guide No. GSG-5

PLANNED EXPOSURE SITUATIONS Occupational exposure

Occupational exposure



Occupational exposure



Exposure of workers incurred in the course of their work.

Any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relations to occupational radiation protection.

Specific requirements on responsibilities of regulatory bodies:

- <u>Requirement 19:</u> The regulatory body shall establish and enforce requirements that protection and safety is optimized, and that doses from occupational exposure comply with dose limits
- <u>Requirement 20:</u> The regulatory body shall establish and enforce requirements for the monitoring and recording of occupational exposure in planned exposure situations

Specific responsibilities of employers, registrants and licensees:

• <u>Requirement 21:</u> Employers, registrants and licensees shall be responsible for the protection of workers against occupational exposure. They shall ensure that protection and safety is optimized and that the dose limits are not exceeded

Compliance by workers:

• <u>Requirement 22</u>: Workers shall fulfil their obligations and carry out their duties for protection and safety.

Occupational exposure: cooperation between employers and registrants and licensees



Requirement 23: Employers and registrants and licensees shall cooperate to the extent necessary for compliance by all responsible parties with the requirements for protection and safety.

Cooperation should include:

- The development of specific restrictions on exposure and others means for ensuring safety are at least as good as for those employees of the licensee
- Specific assessment of doses received by workers
- Clear allocation and documentation of responsibilities of employer and of licensee for protection and safety
- Licensee to obtain from employer previous occupational exposure history of workers
- Provide information to employer that the employer requests
- Provide both the worker and employer with relevant exposure records



If workers are engaged in work that involves or that could involve a source that is not under the control of their employer, the registrant or licensee responsible for the source and the employer shall cooperate to the extent necessary for compliance by both parties with the requirements (e.g. maintenance workers in the nuclear power industry who are employed by a contractor during normal operations, shutdown or maintenance outages)

Occupational exposure – Work Areas



Requirement 24: Employers, registrants and licensees shall establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for occupational exposure.



A defined area in which specific protection measures and safety provisions are or could be required for controlling exposures and preventing the spread of contamination in normal working conditions or limiting extent of potential exposures.



Area for which occupational exposure conditions need to be kept under review, even though specific measures for protection and safety are not normally needed.

GSR Part 3 does not require workers to be classified

Occupational exposure – other arrangements



Requirement 25: Assessment of occupational exposure and workers' health surveillance

Employers, registrants and licensees shall be responsible for making arrangements for assessment and recording of occupational exposures and for workers' health surveillance.

Requirement 26: Information, instruction and training

Employers, registrants and licensees shall provide workers with adequate information, instruction and training for protection and safety.

Requirement 27: Conditions of service

Requirement 28: Special arrangements for protection and safety for female workers and for persons under 18 years of age undergoing training Employers, registrants and licensees shall not offer benefits as substitutes for measures for protection and safety.

Employers, registrants and licensees shall make special arrangements for female workers, as necessary, for protection of the embryo or fetus and breastfed infants. Employers, registrants and licensees shall make special arrangements for protection and safety for persons under 18 years of age who are undergoing training.

Occupational Radiation Protection GSG-7

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Occupational Radiation Protection

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General Safety Guide

No. GSG-7



Implementation of the Requirements on occupational radiation protection in GSR Part 3

Applicable to all areas concerning occupational exposure in all three exposure situations.

Provides information on ORP framework, exposures of workers in different exposure situations, protection of workers in special cases, dose assessment, management system for service providers, occupational exposure control measures as well as health surveillance are also included.

Five annexes: NORM, methods and systems for individual monitoring for assessment of external exposure, workplace monitoring instruments for assessment of external exposure, biokinetic model for assessment of internal exposure and methos for individual monitoring of internal contamination.



PLANNED EXPOSURE SITUATIONS Public exposure

Exposure pathways for members of the public



Source: IAEA Safety Standards Series No. RS-G-1.8 Environmental and Source Monitoring for Purposes of Radiation Protection

Planned exposure situations: public exposure responsibilities



<u>Requirement 29:</u> The government or the regulatory body shall establish the responsibilities of relevant parties that are specific to public exposure, shall establish and enforce requirements for optimization, and shall establish, and the regulatory body shall enforce compliance with, dose limits for public exposure. <u>Requirement 30:</u> Relevant parties shall apply the system of protection and safety to protect members of the public against exposure

Government & regulatory body

- Establish responsibilities of relevant parties,
- Establish and enforce requirements,
- Enforce compliance with dose limits for public exposure,
- Review design criteria and features related to exposure of the public,
- Establish and approve operational limits and conditions including authorized limits on discharges.

Relevant parties

- Apply the system of protection and safety for protection of members of the public,
- Implement and maintain policies and procedure of public protection
- Monitoring programmes,
- Emergency procedures,
- Ensure adequate control of public access.

Registrants and licensees shall ensure that if a source can give rise to external exposure of members of the public shielding and other protective measures, including access control, are provided for restricting public exposure

Public exposure situations: radioactive waste and discharges



<u>Requirement 31</u>: Relevant parties shall ensure that **radioactive waste** and discharges of radioactive material to the environment are managed in accordance with the authorization

Registrants and licensees, in cooperation with suppliers, as appropriate shall ensure that:

- Any radioactive waste generated is kept to the minimum practicable in terms of both activity and volume
- There is separate processing of radioactive waste of different types, where warranted by differences in factors
- Activities for the predisposal management of and for the disposal of radioactive waste are conducted in accordance with the requirements of applicable IAEA standards

Also:

- Shall maintain an inventory of all radioactive waste that is generated, stored, transferred or disposed of
- Shall develop and implement a strategy for radioactive waste management and shall include appropriate evidence that protection and safety is optimized



See also: <u>IAEA Safety Standards Series No.</u> <u>GSR Part 5: Predisposal Management of</u> <u>Radioactive Waste</u> and <u>IAEA Safety Standards Series No. SSR-5:</u> Disposal of Radioactive Waste

Radiation Protection of the Public and the Environment, GSG-8



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General Safety Guide No. GSG-8



CONTENTS

INTRODUCTION

Background (1.1–1.6)..... Objective (1.7) Scope (1.8–1.10)....

Structure (1.11)....

AND THE ENVIRONMENT.

FRAMEWORK FOR THE PROTECTION OF THE PUBLIC

This Safety Guide covers the generic application of the requirements in GSR Part 3 that relate to the protection of the environment and protection of members of the public in planned exposure situations and existing exposure situations and in GSR Part 3 and GSR Part 7 in emergency exposure situations.
 It does not deal with the application of the requirements in GSR Part 3 to specific types of facility or activity or in specific exposure situations, e.g consumer products, non-human medical imaging, discharges, ...

2.



IAEA General Safety Guide No. GSG-9: Regulatory control of Radioactive Discharges to the Environment

A "discharge" is a planned and controlled release of gaseous, aerosol or liquid radioactive substances to the environment and, as such, the term does not include releases to the environment in an accident.

Controllable radioactive releases shall be regulated through a graded approach:

- releases in normal operation that result in very small doses to the public and where there is no risk of an unexpected accidental release, can be managed through the application of the concept of exemption or by means of notification.
- releases may result in doses with a higher level of radiological significance or the facility or activity may present potentially higher radiation risks. In such cases it may be appropriate for the regulation of the releases to be managed by means of an authorization.

IAEA Safety Standards

Regulatory Control of Radioactive Discharges to the Environment

General Safety Guide No. GSG-9



IAEA General Safety Guide No. GSG-10: Prospective Radiological Environmental Impact Assessment for IAEA Facilities and Activities

Objective: the aim of a prospective radiological environmental impact assessment (REIA) is to determine whether the planned facility or activity complies with current legislative and regulatory requirements on the protection of the public and the environment against ionizing radiation under all reasonably foreseeable circumstances.

Assessment for the protection of the public in normal operation

- Selection of the source term
- Modelling of direct irradiation, dispersion and transfer in the environment
- Identification of exposure pathways
- Identification of the representative person for normal operation
- Assessment of the dose to the representative person
- Comparison of estimated dose constraints and dose limits

IAEA Safety Standards for protecting people and the environment

Prospective Radiological Environmental Impact Assessment for Facilities and Activities

UN®

General Safety Guide No. GSG-10



Public exposure situations: Monitoring and reporting



<u>Requirement 32</u>: The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available

The regulatory body

- Reviews and approves the monitoring programmes of licensees
- Review of periodic reports on public exposure submitted by licensees
- Making provision for independent monitoring programmes
- Assessment of total public exposure from authorized sources and practices in the State

The licensees

- Establishes and implements monitoring programmes to ensure that public exposure due to sources is adequately assessed and demonstrate compliance with the authorization. To include monitoring of (i) external exposure (...); (ii) Discharges; (iii) Radioactivity in the environment;
- Maintain appropriate records of the results of the monitoring programmes and estimated doses to members of the public;
- Report or make available to the regulatory body the results...
- Report promptly any levels exceeding authorized limits on discharges ...
- Publish or make available the results

Public exposure situations: consumer products



<u>Requirement 33</u>: Providers of consumer products shall ensure that consumer products are not made available to the public unless their use by members of the public has been justified, and either use has been exempted or their provision to the public has been authorized.

Consumer product:

A device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale.

Examples include:

Smoke detectors, luminous dials, ion generating tubes. It doesn't include the building materials, ceramic tiles, spa waters, minerals and foodstuffs and produces installed in public places (e.g. exit signs).







Planned exposure situations: medical exposure Section 3: Requirements 34-42. Apply to all medical exposures, including intended, unintended and accidental exposures.

 Medical exposure concerns:

 Patients

 Carers and comforters

 Volunteers in a programme of biomedical research

 A patient is an individual who is a recipient of services of health care

professionals and/or their agents that are directed at (a) promotion of health; (b) prevention of illness and injury; (c) monitoring of health; (d) maintaining health; and (e) medical treatment of diseases, disorders and injuries in order to achieve a cure or, failing that, optimum comfort and function. Some asymptomatic individuals are included.

Carers and comforters are persons who willingly and voluntarily help (other than in their occupation) in the care, support and comfort of patients undergoing radiological procedures for medical diagnosis or medical treatment of Ionizing Radiation

Specific Safety Guide No. SSG-46



Planned exposure situations: medical exposure



Requirement 36: Registrants and licensees



- Ensures that relevant parties are **authorized** to assume their roles and responsibilities
- Ensures the establishment of dose constraints and diagnostic reference levels
- Establishes guideline for the release of nuclear medicine patients
- Ensures health professionals fulfil the requirements for education and training and have the competence in radiation protection
- Ensure no person receives a medical exposure without an appropriate referral
- Inform patients of the expected benefits and risks of the medical exposure
- Ensure protection and safety

Medical exposure: radiation protection principles





The main tool for optimization of medical exposures for patients is the diagnostic reference level. Medical workers are subject to the same dose limits as workers.

<u>Dose limits do not apply to medical</u> <u>exposures</u> - exposure of patients, carers or comforters, and volunteers as part of a programme of biomedical research.

Medical exposure: justification



Requirement 37: Relevant parties shall ensure that medical exposures are justified.

<u>Justification</u>: The diagnostic or therapeutic benefits produced by exposures are weighed against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.



Medical exposure: optimization of protection and safety



Requirement 38: Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure.

Optimization principle

The principle of optimization of protection is being applied to every exposure:

- Design considerations for equipment
- Operational considerations
- Calibration
- Dosimetry of patients
- Diagnostic Reference Levels (DRLs)
- Quality assurance
- Dose constraints



Too low a radiation dose could be as bad as too high a radiation dose. It is of paramount importance that the medical exposure leads to the required outcome.

Medical exposure: optimization of protection and safety



Requirement 38: Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure.

Optimization principle



In diagnostic and interventional medical exposure, keeping the exposure of patients to the minimum necessary to achieve the required diagnostic or interventional objective.



In therapeutic medical exposure, keeping the exposure of normal tissue as low as reasonably achievable consistent with delivering the required dose to the planning target volume.

Medical exposure



<u>Requirement 39: Pregnant or breast-feeding female patients</u> Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding

<u>Requirement 40: Release of patients after radionuclide therapy</u> Registrants and licensees shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy

<u>Requirement 41: Unintended and accidental medical exposures</u> Registrants and licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures. Registrants and licensees shall promptly investigate unintended or accidental medical exposures and, if appropriate, shall implement corrective actions.

Requirement 42: Reviews and records

Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained

Medical exposure: Pregnant or breast-feeding patients

Requirement 39: Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding.

Female patients who are to undergo a radiological procedure shall be requested to notify the relevant personnel in the event that:

- She is or might be pregnant
- She is breast-feeding and the scheduled radiological procedures includes the administration of a radiopharmaceutical





The registrants and licensees shall ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity <u>before the performance of any radiological</u> <u>procedure that could result in a significant dose to</u> <u>the embryo or fetus</u>, so that this information can be considered in the justification for the radiological procedure and in <u>the optimization of protection and</u> <u>ssafety</u>.

Medical exposure: Release of patients after radionuclide therapy



Requirement 40: Registrants and licensees shall ensure that there are arrangements in place To ensure appropriate Radiation Protection for members of the public and for family members before a patient is released following radionuclide therapy.

3.178. The radiological medical practitioner shall ensure **that no patient who has undergone a therapeutic radiological procedure** with a sealed source or an unsealed source is discharged from a medical radiation facility **until it has been established** by either a medical physicist or the facility's radiation Protection officer **that**:

- a) The activity of radionuclides in the patient is such that doses that could be received by members of the public and family members would be in compliance with the requirements set by the relevant authorities (para. 3.149(b)); and
- b) The patient or the legal guardian of the patient is provided with:
 - i. Written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination;
 - ii. Information on the radiation risks.



Medical exposure: Unintented and accidental medical exposures



Requirement 41: Registrants and licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures. Registrants and licensees shall promptly investigate unintended or accidental medical exposures and, if appropriate, shall implement corrective actions.

Unintended or accidental exposures may arise from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software or as a result of human error.

With regard to any unitended or accidental medical exposures the registrants and licensees shall:

Calculate or estimate the doses received and the dose distribution within the patient

Indicate the corrective actions to prevent recurrence of such an event

Implement all corrective actions that are under theri own responsibility

Produce and keep a written record that states the cause of the unintended or accidental medical exposure and includes the information specified above, as relevant, and any other information as required by the regulatory body; and for significant unintended or accidental medical exposures or submit this written record, as soon as possible, to the regulatory body, and to the relevant health authority if appropriate.

Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legal authorized representative of the unintended or accidental medical exposure.

Requirement 42: Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained





EMERGENCY EXPOSURE SITUATIONS Covered in dedicated lecture

Emergency exposure situations



Section 4: Requirements 43-46

An emergency exposure situation is a situation of exposure that arises as a result of an accident, a malicious act or any other unexpected event, and requires prompt action in order to avoid or to reduce adverse consequences. Preventive measures and mitigatory actions have to be considered before an emergency exposure situation arises. However, once an emergency exposure situation actually arises, exposures can be reduced only by implementing protective actions.

Justification and optimization of protection measures

Dose limits and emergency dose limits for occupational exposure

Dose reference levels for public exposure



Emergency exposure situations: Transition to existing exposure situation



<u>Requirement 46</u>: The government shall ensure that arrangements are in place and are implemented as appropriate for the transition from an emergency exposure situation to an existing exposure situation.

Emergency exposure situation

<u>The government:</u> arrangements are in place, and are implemented for this transition which shall be made in a coordinated and orderly manner

Existing exposure situation

<u>The responsible authority:</u> shall take the decision to make the transition transfer responsibilities to the appropriate parties in accordance with the government's emergency preparedness plan

Workers involved in the transition:

Requirements for occupational exposures in planned exposure situations apply





EXISTING EXPOSURE SITUATIONS

Existing exposure situations - scope



Section 5: Requirements 47-52

Situations that already exist when a decision on control has to be taken, such as those by natural background radiation and residues from past practices operated outside the system

Contamination or areas by residual radioactive material arising from:



Past activities that were never subject to regulatory control



A nuclear or radiological emergency, after emergency has been terminated

Exposure due to radionuclides in:





Food, drinking water, animal feed, construction materials and other commodities

Exposures due to natural sources:



Radon with respective progeny



Natural radionuclides in commodities



Radionuclides of uranium or thorium chain \leq 1 Bq/g and K-40 \leq 10 Bq/g



Exposure of aircrew and space crew

Existing exposure situations



Section 5: Requirements 47-52

Worldwide distribution of radiation exposure





The global average annual effective dose per person is about 2.4 mSv. About 80% of this dose is due to natural sources.

Existing exposure situations: responsibility



<u>Requirement 47</u>: The government shall ensure that **existing exposure situations that have been identified are evaluated** to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection

The government

Identifies the exposures of concern

Ensures assignment of responsibilities

Identifies responsible parties for site remediation and put in place waste management strategies

Provides for involvement of interested parties

Ensures establishment of reference levels

Gathers and provides information on exposure levels to radon and health risks to the public

Regulatory body or other relevant authority

Implements protection of strategies

Ensures that remedial and protective actions are justified and optimized

Establishes references levels

Is responsible for authorization or remediation

<u>Requirement 48</u>: Justification for protective actions and optimization of protection and Safety The government and the regulatory body or other relevant authority shall ensure that remedial actions and protective actions are justified and that protection and safety is optimized.
Existing exposure situations – reference level



Reference level is the level of **dose, risk or activity concentration** above which it is not appropriate to plan to allow exposures to occur and below which optimization of protection and safety would continue to be implemented.



Reference levels are not limits – but should initiate action if exceeded

Public exposure: responsibilities for remediation of areas with residual radioactive material



<u>Requirement 49</u>: The government shall ensure that provision is made for identifying those persons or organizations responsible for areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures, if appropriate; and for putting in place an appropriate strategy for radioactive waste management.



The government is responsible for ensuring that provision is made to:

- Identify those persons or organizations responsible for areas with residual radioactive material
- Establish and implement a remediation programme and post-remediation control measures
- Establish an appropriate strategy for radioactive waste management



Remedial action plan includes:

- Sharing of public information
- Establishing and implementing a monitoring programme
- Maintaining records



<u>Requirement 50</u>: The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors.



IAEA Safety Standards for protecting people and the environment

Protection of the Public against Exposure Indoors due to Radon and Other Natural Sources of Radiation

Jointly sponsored by the IAEA, WHO

Specific Safety Guide No. SSG-32



If there are significant radon levels, then the national action plan shall be established

Exposure due to radionuclides in commodities



<u>Requirement 51</u>: The regulatory body or other relevant authority shall establish reference levels for **exposure due to radionuclides in commodities**.



- Specific reference levels for exposure due to radionuclides in commodities such as construction materials, food and feed, and in drinking water, each of which shall typically be expressed as, or be based on, an annual effective dose to the representative person that generally does not exceed a value of about 1 mSv.
- Consider the "guideline levels" for radionuclides in food traded internationally that could contain radioactive substances as a result of a nuclear or radiological emergency, published by the Joint FAO/WHO Codex Alimentarius Commission and the "guidance levels" for radionuclides in drinking water published by WHO.

Exposure in workplaces – existing exposure situation



<u>Requirement 52</u>: The regulatory body shall establish and enforce requirements for the protection of workers in existing exposure situations.

Requirements in respect of public exposure shall be applied for protection and safety for workers in existing exposure situations, other than in those specific situations which include:

- Situations involving the remediation of areas with residua radioactive material
- Exposure of aircrew and space crew to cosmic radiation
- Protection of workers against exposure to radon under development

IAEA Safety Standards

Protection of Workers Against Exposure Due to Radon

New Safety Guide

Under development (DS519)

- Employers shall ensure that activity concentrations of 222Rn in workplaces are as low as reasonably achievable below the reference level established set at a value that does not exceed an annual average activity concentration of 222Rn of 1000 Bq/m3, and shall ensure that protection is optimized
- If, despite all reasonable efforts by the employer to reduce activity concentrations of radon, the activity concentration of 222Rn in workplaces remains above the reference level, the relevant requirements for occupational exposure in planned exposure situations as stated in Section 3 of GSR Part 3 shall apply

GSR Part 3 overall structure



Section 1: Introduction

Section 2: General Requirements for Protection and Safety (Requirements 1-5)

- Section 3: Planned Exposure Situations
 - Generic requirements (Requirements 6-18)
 - Occupational Exposure (Requirements 19-28)
 - Public Exposure (Requirements 29-33)
 - Medical Exposure (Requirements 34-42)
- Section 4: Emergency Exposure Situations (Requirements 43-46)
- Section 5: Existing Exposure Situations

(Requirements 47-52)

IAEA Safety Standards

for protecting people and the environment

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

Jointly sponsored by EC, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP, WHO

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General Safety Requirements Part 3 No. GSR Part 3



SCHEDULE I:EXEMPTION AND CLEARANCESCHEDULE II:CATEGORIES FOR SEALED SOURCES USED IN COMMON PRACTICESSCHEDULE III:DOSE LIMITS FOR PLANNED EXPOSURE SITUATIONSSCHEDULE IV:CRITERIA FOR USE IN EMERGENCY PREPAREDNESS AND RESPONSE

REFERENCES

ANNEX: GENERIC CRITERIA FOR PROTECTIVE ACTIONS AND OTHER RESPONSE ACTIONS TO REDUCE THE RISK OF STOCHASTIC EFFECTS.

DEFINITIONS

Annex



Supporting guidance to GSR Part 3

IAEA Radiation Protection and Safety Guidance



"The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation."

> IAEA Fundamental Safety Principles

The IAEA develops safety standards and supporting technical documents that cover all areas relevant to safety related to a wide range of nuclear material and facilities.

> Public / Workers / Environment / Patients / Other



IAEA Safety Standards IAEA Safety Standards IAEA Safety Standards IAEA Safety Standards for protecting people and the environ for protecting people and the envi ecting people and the env tecting people and the env Radiation Safety of **Radiation Safety** Radiation Protection and Radiation Safety in Accelerator Based of Gamma, Electron Safety in Medical Uses Industrial Radiography Radioisotope Production and X Ray Irradiation of Ionizing Radiation Facilities Jointly sponsored by Facilities 00000 IAEA Safety Standards for protecting people and the environment Specific Safety Guide Specific Safety Guide Specific Safety Guide Specific Safety Guide No. SSG-59 No. SSG-8 No. SSG-46 No. SSG-11 () IAEA (A)IAEA () IAEA Occupational Workers () IAEA **Radiation Protection** Jointly sponsored by 2018 2011 2010 2020 update in update in progress progress General Safety Guide No. GSG-7 IAEA Safety Standards for protecting people and the environment IAEA Safety Standards IAEA Safety Standards for protecting people and the environment ting people and the envi (A) IAEA Protection of **Radiation Safety** Radiation Safety Workers Against in the Use of in Well Logging 2018 Exposure Due Nuclear Gauges to Radon New Safety Specific Safety Guide Specific Safety Guide No. SSG-57 No. SSG-58 Guide () IAEA () IAEA Under development 2020 2020

(DS519)





Safety Guides & other IAEA publications supporting GSR Part 3





IAEA Safety Standards for protecting people and the environment

Establishing the Infrastructure for Radiation Safety IAEA Safety Standards for protecting people and the environment

Categorization of Radioactive Sources

Safety Guide No. RS-G-1.9

(A)IAEA

IAEA Safety Standards for protecting people and the environment

Safety of Radiation Generators and Sealed Radioactive Sources

Other

Specific Safety Guide No. SSG-44

2018

IAEA Safety Standards for protecting people and the environment

National Strategy for Regaining Control over Orphan Sources and Improving Control over Vulnerable Sources

Specific Safety Guide No. SSG-19

2012 update agreed by RASSC 2005 update agreed by RASSC

IAEA Safety Standards for protecting people and the environment

Control of Orphan Sources and Other Radioactive Material in the Metal Recycling and Production Industries

Specific Safety Guide No. SSG-17

() IAEA

2012 update agreed by RASSC Safety Guide No. RS-G-1.10

2006

IAEA Safety Standards for protecting people and the environment

Radiation Safety of Sources used in Research and Education

SSG-87

In pre-print repository



IAEA Safety Standards

IAEA Safety Standards

Revision of

Radiation Protection and Safety in Existing Exposure Situations

New General Safety Guide

Under development

IAEA Safety Series No. 1 on Safe Handling of Radionuclides (updated version in 1973)

New General Safety Guide

Public

















How to contact us

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Thank you!

