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Radiation Protection of the Public and Protection of the Environment

DRAFT SAFETY GUIDE

DS432

New Safety Guide

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FOREWORD

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1. INTRODUCTION

BACKGROUND

1.1. The fundamental safety objective given in IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [1] is "to protect people and the environment from harmful effects of ionizing radiation". It applies to all circumstances that give rise to radiation risks. The fundamental safety objective is associated with ten safety principles [1]. Virtually all of these safety principles touch on the protection of members of the public and the environment. Principle 7 in particular states that "People and the environment, present and future, must be protected against radiation risks".

1.2. General requirements designed to protect members of the public and the environment from harmful effects of ionizing radiation are established in IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [2]. The requirements for the governmental, legal and regulatory framework to be used are established in IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [3]. The requirements for emergency preparedness and response are established in IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [4].

1.3. Radiation protection has been largely focused on the protection of humans and, for this purpose, three basic categories of exposure have been considered, namely occupational exposure, medical exposure and public exposure. The relevant radiation protection requirements are defined according to the exposure situation, namely planned exposure situations, emergency exposure situations or existing exposure situations.

1.4. Public exposure is defined as 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 [2]. GSR Part 3 [2] defines a member of the public as "any individual in the population except when subject to occupational exposure or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, this is the representative person". GSR Part 3 [2] defines a representative person as "an individual receiving a dose that is representative of the doses to the more highly exposed individuals in the population".

1.5. In recent years, consideration has also been given to the protection of the environment. As noted by the International Commission on Radiological Protection (ICRP) [5, 6, 7], some

national regulatory frameworks have already addressed the need to be able to demonstrate that the environment is protected against harmful effects of ionizing radiation, irrespective of any human connection with the environment. The methods and criteria for radiological assessments are being developed and will continue to evolve.

1.6. This General Safety Guide provides generic guidance on the application of the requirements of GSR Part 3 [2] and GSR Part 7 [4] in relation to the protection of members of the public in planned exposure situations, existing exposure situations and emergency exposure situations and protection of the environment that is applicable for all facilities and activities.

OBJECTIVE

1.7. The objective of this Safety Guide is to provide generic guidance on the application of the requirements for the protection of members of the public against radiation exposure and protection of the environment established in GSR Part 3 [2] and GSR Part 7 [4]. It is intended for use by:

(a) Governments;
(b) Regulatory bodies;
(c) Registrants and licensees, or the person or organization responsible for facilities and activities for which notification only is required in planned exposure situations;
(d) Those persons or organizations designated to deal with emergency exposure situations or existing exposure situations.

SCOPE

1.8. This Safety Guide covers the generic application of the requirements given in GSR Part 3 [2] 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 [2] and GSR Part 7 [4] in emergency exposure situations.

1.9. This Safety Guide does not deal with the application of the requirements in GSR Part 3 [2] to specific types of facility or activity or in specific exposure situations. In this context, separate Safety Guides exist or are under development such as: for planned exposure situations: Justification of Practices, including Non-Medical Human Imaging (GSG-5) [8], Prospective Radiological Environmental Impact for Facilities and Activities (DS427) [9], Regulatory Control of Radioactive Discharges to the Environment (DS442) [10], Radiation Safety for Consumer Products (SSG-36) [11]; for emergency exposures situations: Criteria for

Use in Preparedness and Response for a Nuclear or Radiological Emergency (GSG-2) [12], Arrangements for Preparedness for a Nuclear or Radiological Emergency (GS-G-2.1) [13]; and for existing exposure situations: Remediation Process for Areas Affected by Past Activities and Accidents (WS-G-3.1) [14] and Protection of the Public against Exposure Indoors due to Radon and Other Natural Sources of Radiation (SSG-32) [15].

1.10. Occupational exposure and medical exposure are not considered in this Safety Guide; the relevant recommendations are provided in Occupational Radiation Protection (DS453) [16] and in Radiation Protection and Safety in Medical Uses of Ionizing Radiation (DS399) [17].

STRUCTURE

1.11. Section 2 provides an overview of the basic framework for radiation protection of members of the public and protection of the environment in planned exposure situations, emergency exposure situations and existing exposure situations. It covers the principles of justification, optimization of protection, and dose limits, where appropriate. Section 3 deals with practical application of the radiation protection framework for protection of the public in planned exposure situations, emergency exposure situations and existing exposure situations. Section 4 provides guidance on meeting the requirements of GSR Part 3 [2] for protection of the environment. The Appendix summarizes the framework for dose constraints and reference levels as applicable for each exposure situation, in accordance with GSR Part 3 [2].

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2. FRAMEWORK FOR THE PROTECTION OF THE PUBLIC AND PROTECTION OF THE ENVIRONMENT

INTRODUCTION

2.1. Paragraph 2.15 of GSR Part 3 [2] requires the scope of applicability of the legal and regulatory framework to be specified. The regulatory framework established in GSR Part 3 [2] applies to all situations involving radiation exposure that is amenable to control. Exposures that are deemed to be unamenable to control are excluded from the regulatory framework. Examples of exposures that are unamenable to control are ^{40}K in the body and cosmic radiation at the surface of the Earth.

2.2. GSR Part 3 [2] establishes requirements for each of the three exposure situations: planned exposure situations, emergency exposure situations and existing exposure situations. In addition, in the context of emergency exposure situations, GSR Part 7 [4] establishes requirements for an adequate level of preparedness and response for a nuclear or radiological emergency.

EXPOSURE SITUATIONS

Planned exposure situations

2.3. A planned exposure situation is a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source. Since provision for protection and safety can be made before embarking on the activity concerned, the associated exposures and their likelihood of occurrence can be restricted from the outset. The primary means of controlling exposure in planned exposure situations is by good design of facilities, equipment and operating procedures, by training and by fostering safety culture [2, 18].

2.4. In planned exposure situations, exposure at some level can be expected to occur. If exposure is not expected to occur with certainty, but could result from an anticipated operational occurrence or accident or owing to an event or a sequence of events that may potentially occur but is not certain to occur, this is referred to as ‘potential exposure’. The magnitude and extent of potential exposure can usually be predicted. Both exposures expected to occur and potential exposures can and should be taken into account at the planning or design stage.

2.5. A term closely related to planned exposure situation is the term practice, which is defined as any human activity that introduces additional sources of exposure or additional

exposure pathways or extends exposure to additional people, or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed [19]. Both terms are used in GSR Part 3 [2], although the term planned exposure situation emphasizes the planned or intentional nature of the facility or activity that may give rise to radiation exposure.

Emergency exposure situations

2.6. 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 reduce adverse consequences [2]. 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.

Existing exposure situations

2.7. An existing exposure situation is a situation of exposure that already exists when a decision on the need for control needs to be taken [2]. Existing exposure situations include situations of exposure to natural background radiation. They also include situations of exposure due to residual radioactive material that derives from past practices that were never subject to regulatory control or that were subject to regulatory control but not in accordance with the requirements of current standards, situations of exposure due to residual radioactive material deriving from a nuclear or radiological emergency after an emergency has been declared to be ended, and situations of exposure due to commodities incorporating radionuclides from such material.

RADIATION PROTECTION PRINCIPLES

2.8. The three basic principles that underpin radiation protection, which concern justification, optimization of protection and safety, and application of dose limits, are expressed in Safety Principles 4, 5, 6 and 10 of SF-1 [1]. The principles of justification and optimization of protection and safety relate to sources of ionizing radiation and apply to all exposure situations. The principle of application of dose limits relates to individuals and applies to public exposure in planned exposure situations only. Requirement 1 of GSR Part 3 [2] requires that those responsible for protection and safety ensure that these principles of radiation protection are applied for all exposure situations.

Justification

2.9. Paragraph 2.8 of GSR Part 3 [2] states that

> "For planned exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that no practice is undertaken unless it is justified."

2.10. Paragraph 2.9 of GSR Part 3 [2] states that

> "For emergency exposures situations and existing exposures situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, protective actions and remedial actions are justified and are undertaken in such a way as to achieve the objectives set out in a protection strategy."

2.11. For planned exposure situations, justification is the process of determining if the expected benefits to humans and to society from introducing or continuing a planned activity involving ionizing radiation outweigh the harm, including radiation detriment, resulting from the activity. The benefits apply to individuals and society as a whole, and include benefits to the environment. Radiation detriment may only be a small part of the total harm. Justification thus goes far beyond the scope of radiation protection, and also involves the consideration of economic, societal and environmental factors [5].

2.12. For emergency exposure situations, when considering the justification of proposed protection actions and the overall protection strategy, para. 4.29 of GSR Part 7 [4] states that

> "Each protective action, in the context of the protection strategy, and the protection strategy itself shall be demonstrated to be justified (i.e. to do more good than harm), with account taken not only of those detriments that are associated with radiation exposure but also of those detriments associated with impacts of the actions taken on public health, the economy, society and the environment."

2.13. Decisions regarding justification should be taken at a sufficiently high governmental level to enable all of the considerations that may be related to the benefits and detriments to be integrated. Thus, while the regulatory body or other national authority concerned with radiation protection should be responsible for evaluating the assessment of the radiation detriment, it may not be in a position to make the justification decision. Any justification decision should therefore always involve a consideration of the radiation doses either to be incurred or to be averted or reduced according to the circumstances. In planned exposure situations, radiation risks from potential exposures are required also to be considered in the justification decision.

Optimization of protection and safety

2.14. Paragraph 2.10 of GSR Part 3 [2] states that

> "For all exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that protection and safety is optimized."

2.15. 'Protection and safety is optimized' in this context means that optimization of protection and safety has been applied and the result of that process has been implemented.

2.16. Optimization of protection and safety is defined as the process for determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure being "as low as reasonably achievable, economic and social factors being taken into account" (ALARA). This means that the level of protection would be the best possible under the prevailing circumstances, and will thus not necessarily be the option with the lowest risk or dose. Protection of the environment should also be considered in the process of optimization of protection and safety.

2.17. Protection and safety should be optimized through an on-going cyclical approach that involves:

(a) Evaluation of the exposure situation to identify the need for action;

(b) Identification of possible protective actions to keep the exposure as low as reasonably achievable;

(c) Selection of the best protective actions under the prevailing circumstances;

(d) Implementation of the selected protective actions;

(e) Regular review of the exposure situation to evaluate whether the prevailing circumstances necessitate any changes to the selected protective actions.

2.18. For planned exposure situations, Requirement 11 of GSR Part 3 [2] states that

> "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".

Paragraph 3.23 of GSR Part 3 [2] requires registrants and licensees to ensure that protection and safety is optimized.

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2.19. For emergency exposure situations, Requirement 44 of GSR Part 3 [2] and Requirement 5 of GSR Part 7 [4] require the government to ensure that protection strategies are developed, justified and optimized at the stage for taking protective actions and other response actions effectively. Paragraph 4.31 of GSR Part 7 [4] states further that the government is also required to ensure that the protection strategy is implemented safely and effectively in an emergency response through the implementation of emergency arrangements.

2.20. For existing exposure situations, Requirement 48 of GSR Part 3 [2] requires the government and the regulatory body or other relevant authority to ensure that protection and safety is optimized.

2.21. In all three exposure situations, the process of justification and optimization should, when possible, include consultation with interested parties, such as community groups, local residents and members of the public.

Boundary conditions for optimization

2.22. Optimization of protection is a prospective, iterative process that examines the available options for protection. Depending upon the circumstances, the process can include the use of a variety of quantitative and qualitative techniques. Optimization should be conducted within a set of boundary conditions on the range of available protection options. These boundary conditions should include individual source related values of dose or risk that may be regarded as values that should not be exceeded for planning purposes. They are referred to as dose constraints or risk constraints in the case of planned exposure situations and as reference levels in the case of emergency exposure situations or existing exposure situations.

2.23. A constraint is a prospective and source related value of individual dose (dose constraint) or risk (risk constraint) that is used in planned exposure situations as a parameter for the optimization of protection and safety for the source, and that serves as a boundary condition in defining the range of options in optimization.

2.24. A dose constraint is a level of dose above which it is unlikely that protection is optimized. It represents a basic level of protection and will always be lower than the pertinent dose limit. However, treating a dose constraint as a target value is not sufficient, and it is expected that optimization of protection will establish an acceptable level of dose below the dose constraint.

2.25. Risk constraints correspond to dose constraints but apply to potential exposure. The risk constraint is a source related value that provides a basic level of protection for the individuals most at risk from a source. This risk is a function of the probability of an unintended event causing a dose and the probability of the detriment due to such a dose. The risk constraint should equate to a similar health risk to that implied by the corresponding dose constraints for the same source [5, 20]. However, there can be large uncertainties in estimations of the probabilities and the resulting dose, which should be taken into account at the time of defining and using the risk constraints for decision making or decision aiding.

2.26. Reference level is defined as, for an emergency exposure situation or an existing exposure situation, 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. The value chosen for a reference level will depend upon the prevailing circumstances for the exposure under consideration. In practice, reference levels for some situations are likely to be established on the basis of one or more exposure scenarios. As such the chosen reference levels are dependent on the assumptions used in their determination, and may not be universally applicable.

2.27. In an emergency exposure situation or in an existing exposure situation, actual exposures could be above or below the reference level. The reference level should then be used as a benchmark for judging the extent to which protective actions are necessary and to assist in prioritizing their application. Optimization of protection and safety is to be applied even if the initial estimate of the doses received are below the defined reference levels, if justified and optimized actions are available to reduce exposures. Further recommendations on the application of the concept of the reference level in an emergency exposure situation for dosimetric purposes, in addition to the use of generic criteria, are given in Section 3.

2.28. In an emergency exposure situation or in an existing exposure situation, the implementation of optimized protection strategies should result in levels of dose, risk or activity concentration below the reference level and as low as reasonably achievable, as long as these protection strategies are justified, with account taken of national factors.

2.29. The requirements of GSR Part 3 [2] for optimization of protection and safety, including the use of dose constraints and reference levels, for each of the three exposure situations, are presented in Section 3. A table summarizing the values for the dose constraints and for reference levels as applicable for each exposure situation as required in GSR Part 3 [2] is presented in the Appendix.

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Dose limits

2.30. Paragraph 2.11 of GSR Part 3 [2] states that

> "For planned exposure situations other than medical exposure, each party with responsibilities for protection and safety shall ensure that, when relevant requirements apply to that party, specified dose limits are not exceeded".

2.31. Dose limits apply for exposure of workers and for public exposure in planned exposure situations only. Dose limits for members of the public are presented in Section 3. Dose limits do not apply for medical exposures. The annual effective dose to members of the public, for comparison with the dose limit for effective dose, is the sum of the effective dose obtained within one year from external exposure and the committed effective dose from internal exposure within this year.

2.32. Doses to members of the public are usually not obtained by individual monitoring, as for occupational exposure, but are generally estimated using the predictions of models that simulate the transport of radionuclides in the environment combined with data on habits of members of the public for relevant exposure scenarios and dose coefficients.

RESPONSIBILITIES

Responsibilities of the government

2.33. The responsibilities of the government with regard to protection and safety for all three exposure situations are established in general terms in paras 2.13–2.28 of GSR Part 3 [2]. These include:

(a) Establishing an effective legal and regulatory framework for protection and safety in 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 arrangements are in place for the provision of technical services and education and training services.

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2.34. The responsibilities of the government or the regulatory body with regard to protection of the public in planned exposure situations are set out in Requirement 29 and in paras 3.118–3.121 and 3.124 of GSR Part 3 [2]. These responsibilities include:

(a) Establishing the responsibilities of registrants, licensees and suppliers and of providers of consumer products in relation to the application of requirements for public exposure in planned exposure situations;

(b) Establishing and enforcing requirements for the optimization of protection and safety, including establishing or approving constraints on dose and constraints on risk to be used in the optimization of protection and safety for members of the public;

(c) Establishing dose limits for public exposure in planned exposure situations.

2.35. The responsibilities of the government for protection of the public in emergency exposure situations are set out in Requirements 43 and 44 of GSR Part 3 [2] in general terms, and in greater detail in GSR Part 7 [4]. Some of the responsibilities of the government include:

(a) Establishment of an integrated and coordinated emergency management system;

(b) Development of justified and optimized protection strategies at the preparedness stage;

(c) Ensuring safe and effective implementation of emergency arrangements in accordance with the protection strategy.

In addition to assigning responsibilities to the government in general terms, GSR Part 3 [2] and GSR Part 7 [4] assign specific responsibilities in emergency preparedness and response to response organizations.

2.36. The responsibilities of the government for protection of the public in existing exposure situations are set out in Requirements 47, 48, 49 and 50 of GSR Part 3 [2]. The government is required to ensure that existing exposure situations that have been identified are evaluated to determine which public exposures are of concern from the point of view of radiation protection; and to ensure that remedial actions and protective actions are justified and that the protection and safety is optimized. The government is required to ensure that provision for the management of existing exposure situations is included in the legal and regulatory framework for protection and safety. The government, in the legal and regulatory framework, is required to assign responsibilities for the establishment and implementation of protection strategies to the regulatory body and to other relevant authorities, and as appropriate, to registrants,

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licensees and other parties involved in the implementation of remedial actions and protective actions.

Responsibilities of the regulatory body

2.37. The responsibilities of the regulatory body with regard to protection and safety that are applicable to all three exposure situations are set out in Requirements 16–36 of GSR Part 1 (Rev. 1) [3] and in Requirement 3 and paras 2.29–2.38 of GSR Part 3 [2]. These responsibilities include: (a) establishing requirements for applying the principles of radiation protection; (b) establishing a regulatory system that meets specified requirements; (c) ensuring the application of the requirements for education and training in protection and safety; (d) specifying acceptance requirements and performance requirements for protection and safety; and (e) making provision for the establishment and maintenance of records.

2.38. The responsibilities of the regulatory body specific to protection of the public in planned exposure situations are set out in Requirements 29 and 32, and in paras 3.118–3.124, 3.135, 3.136, and 3.139 of GSR Part 3 [2]. The regulatory body is responsible for enforcing compliance with the dose limits for public exposure; for authorization of practices; for establishing or approving authorized limits for discharges; for ensuring that programmes for source monitoring and environmental monitoring are in place, and that the results from the monitoring are recorded and are made available; and for authorizing the provision to the public of consumer products.

2.39. The responsibilities of the regulatory body in relation to emergency preparedness and response are set out in paras 4.11–4.15 of GSR Part 7 [4]. These responsibilities include:

(a) To ensure that arrangements for preparedness and response to a nuclear or radiological emergency are dealt with through the regulatory process;

(b) To establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based;

(c) To require that arrangements for preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions;

(d) To establish reference levels;

(e) To ensure that the on-site emergency arrangements are adequate;

(f) To ensure that the operating organization is given sufficient authority to promptly take necessary protective actions on the site in response to a nuclear or radiological emergency.

2.40. The responsibilities of the regulatory body or other relevant authority specific to protection of the public in existing exposure situations are set out in paras 5.4 and 5.5 and in Requirements 48 and 51 of GSR Part 3 [2]. These responsibilities include:

(a) To establish and implement a protection strategy for an existing exposure situation commensurate with the associated radiation risks;

(b) To ensure that remedial actions or protective actions are expected to yield sufficient benefits to outweigh the detriments associated with taking them;

(c) To ensure that the form, scale and duration of remedial actions or protective actions are optimized;

(d) To establish reference levels for exposure due to radionuclides in commodities;

(e) To establish and to review reference levels periodically.

2.41. It is the responsibility of the regulatory body in relation to protection of the environment to specify requirements for the prospective assessment of radiological environmental impacts, as set out para. 3.9 (e) of GSR Part 3 [2].

Responsibilities of registrants and licensees, and operating organizations

2.42. Requirement 4 of GSR Part 3 [2] states that

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

2.43. Requirement 9 of GSR Part 3 [2] states that

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

2.44. Registrants and licensees are required to ensure that protection and safety is optimized and that relevant constraints are used in the optimization of protection and safety for any source within a practice (para. 3.25 of GSR Part 3 [2]).

2.45. Registrants and licensees are required to ensure that exposures of individuals due to practices for which registrants and licensees are authorized are restricted, so that neither the

effective dose nor the equivalent dose to tissues or organs exceeds any relevant dose limit specified in Schedule III of GSR Part 3 [2].

2.46. Registrants and licensees are required to 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 [2].

2.47. In GSR Part 7 [4], the term 'operating organization' is used in this context. The responsibilities of the operating organization in relation to emergency preparedness and response are set out in GSR Part 7 [4], particularly in paras 4.16–4.17.

2.48. Further guidance on the responsibilities of the government, the regulatory body and other national authorities, and of the registrant or licensee or operating organization are provided in Section 3 and in Section 4.

GRADED APPROACH

2.49. GSR Part 3 [2] establishes requirements for a graded approach to be taken to the control of exposures. In particular, para. 2.12 of GSR Part 3 [2] 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."

2.50. It is the general responsibility of the government to ensure that the overall application of the principles of radiation protection are in line with this graded approach (see para. 2.18 of GSR Part 3 [2]). The regulatory body is responsible for adopting the graded approach in the application of the regulatory requirements (see para. 2.31 of GSR Part 3 [2]).

2.51. Requirement 6 of GSR Part 3 [2] refers to the graded approach in the context of planned exposure situations. "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." An important feature of the graded approach in planned exposure situations is the provision for exemption and clearance, and for notification, authorization by registration and authorization by licensing. These concepts are discussed further in Section 3.

2.52. Requirement 4 of GSR Part 7 [4] states that

> "The government shall ensure that a hazard assessment is performed to provide a basis for a graded approach in preparedness and response for a nuclear or radiological emergency."

2.53. Paragraph 5.7 of GSR Part 3 [2] states that

> "The government and the regulatory body or other relevant authority shall ensure that the protection strategy for the management of existing exposure situations …. is commensurate with the radiation risks associated with the existing exposure situation".

2.54. The application of a graded approach in each exposure situation is discussed further in Section 3.

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3. RADIATION PROTECTION OF THE PUBLIC

PLANNED EXPOSURE SITUATIONS

Introduction

3.1. Requirements 3.1 to 3.4 of GSR Part 3 [2] set out the practices and sources within practices that are included in the scope of planned exposure situations. Practices include:

(a) The production, supply, provision and transport of radioactive material and of devices that contain radioactive material;
(b) The production and supply of devices that generate radiation;
(c) The generation of nuclear power, including any activities within the nuclear fuel cycle that involve or that could involve exposure to radiation or exposure to radioactive material;
(d) The use of radiation or radioactive material for medical, industrial, veterinary, agricultural, legal or security purposes;
(e) The use of radiation or radioactive material for education, training or research;
(f) The mining and processing of raw materials that involve exposure due to radioactive material;
(g) Any other practice as specified by the regulatory body.

3.2. Sources within practices include:

(a) Facilities that contain radioactive material and facilities that contain radiation generators, such as nuclear installations, medical radiation facilities, facilities for the management of radioactive waste and mineral extraction and processing facilities; and
(b) Individual sources of radiation, including the sources within the types of facility mentioned in para. 3.2(a).

3.3. Exposure due to natural sources is in general considered in GSR Part 3 [2] to be an existing exposure situation. However, para. 3.4 of GSR Part 3 [2] states that the relevant requirements for planned exposure situations apply, inter alia, to:

(a) Exposure due to material in any practice where the activity concentration in the material of any radionuclide in the uranium decay chain, the actinium decay chain or the thorium decay chain is greater than 1 Bq/g or the activity concentration of ^{40}K is greater than 10 Bq/g (exposure situations due to radionuclides of natural origin in food, feed, drinking water, agricultural fertilizer and soil amendments, construction material and existing residues should be treated as existing exposure situations);

(b) Public exposure due to discharges or due to the management of radioactive waste arising from a practice involving material as specified in para. 3.3(a).

3.4. Public exposures in planned exposure situations arise from:

(a) Liquid and airborne discharges from facilities (see DS442 [10]);

(b) Direct radiation from sources within practices, e.g. X ray equipment in a medical facility, a patient released from hospital after radionuclide therapy, industrial radiography, the transport of radioactive material, the management of solid radioactive waste;

(c) Consumer products (see SSG-36 [11]).

3.5. Paragraph 3.78 of GSR Part 3 [2] states that

> "Employers, registrants and licensees shall ensure that workers exposed to radiation from sources within a practice that are not required by or directly related to their work have the same level of protection against such exposure as members of the public".

Therefore the dose limits and dose constraints for exposure of members of the public apply for such workers.

3.6. For sources that are included in the regulatory system, appropriate tools for application of the requirements for radiation protection and safety, based on a graded approach, are exemption and clearance, notification, and authorization; authorization may take the form of either registration or licensing.

Exemption and clearance

3.7. Exemption is defined as 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 [2]. Only justified practices may be exempted.

3.8. The general criteria for exemption, specified in Schedule I of GSR Part 3 [2], are that:

(a) Radiation risks arising from the practice or from a source within the practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations that could lead to a failure to meet the general criterion for exemption; or

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(b) Regulatory control of the practice or the source would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or of health risks.

3.9. Under these criteria, a practice or a source within a practice may be exempted without further consideration from some or all of the requirements of GSR Part 3 [2] provided that the effective dose expected to be incurred by any individual (para. I.2 of GSR Part 3 [2]) owing to the exempt practice or the exempt source within the practice:

- Is of the order of 10 μSv or less in a year under all reasonably foreseeable circumstances;
- Does not exceed 1 mSv in a year for low probability scenarios[1].

3.10. Clearance is defined as the removal of regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized practices. The general criteria for clearance parallel those for exemption, are also provided in Schedule I of GSR Part 3 [2] and are that:

(a) Radiation risks arising from the cleared material are sufficiently low as not to warrant regulatory control, and there is no appreciable likelihood of occurrence for scenarios that could lead to a failure to meet the general criterion for clearance; or

(b) Continued regulatory control of the material would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or reduction of health risks.

3.11. Under these criteria, material may be cleared without further consideration under the terms of para. 3.14(a) provided that in reasonably foreseeable circumstances the effective dose expected to be incurred by any individual owing to the cleared material is of the order of 10 μSv or less in a year. To take into account low probability scenarios, a different criterion can be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

3.12. Based on the criteria for exemption and clearance, Schedule I of GSR Part 3 [2] presents activity concentrations and activities of radionuclides for moderate amounts of material that may be exempted (Table I.1 of GSR Part 3 [2]) without further consideration

[1] The individual dose criterion for low probability scenarios is based on the assumption that the probability of occurrence of such a scenario does not exceed 10^{-2} per year [21].

from some or all of the requirements of GSR Part 3 [2], and activity concentrations of radionuclides of artificial origin for bulk amounts of solid material that may be exempted and solid material that can be cleared (Table I.2 of GSR Part 3 [2]) without further consideration.

3.13. Paragraph I.3(c) of GSR Part 3 [2] provides for the exemption of radiation generators of a type approved by the regulatory body, and para. I.6 of GSR Part 3 [2] provides for the exemption of equipment containing radioactive material if it is of a type approved by the regulatory body and the material is not otherwise exempted on the basis of its activity (Table I.1 of GSR Part 3 [2]).

3.14. The provision in GSR Part 3 [2] for the exemption of equipment containing sealed radioactive sources can be applied to consumer products. While there a limit applies to dose rate outside the equipment, no limit applies to the activity of the sealed source. Thus, for example, smoke detectors containing ionization chambers with higher levels of activity than those specified for exemption can still be exempted without further consideration provided that the conditions stipulated by the regulatory body in respect of dose rate and other criteria are met and they are of a type approved by the regulatory body [11].

3.15. Schedule I of GSR Part 3 [2] provides also for the exemption and clearance of material containing radionuclides of natural origin. Table I.3 of GSR Part 3 [2] establishes activity concentration levels for material containing natural radionuclides that may be cleared without further consideration. Based on a dose criterion of the order of 1 mSv, commensurate with typical doses due to natural background levels of radiation, para. I.4 of GSR Part 3 [2] provides for the exemption of bulk amounts of material on a case by case basis and para. I.12(c) of GSR Part 3 [2] provides for the clearance of residues for recycling into construction materials or for which disposal is liable to cause the contamination of drinking water supplies.

3.16. Further guidance on exemption and clearance may be found in RS-G-1.7 [22].

Notification and authorization

3.17. Within a graded approach for protection of the public and the environment, notification to the regulatory body alone

> "is sufficient provided that the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible" (para. 3.7 of GSR Part 3 [2]).

3.18. The exposure and risk associated with activities subject to notification is, by definition, so small as not to warrant many or sometimes any additional control measures to ensure protection of the public and protection of the environment. Decisions regarding the use of notification alone should be based on a generic assessment of safety. The doses expected from notified activities should be sufficiently low that there is no need for further consideration regarding public exposures or for investigations or assessments with respect to environmental protection. Notification is not required for exempted sources or practices.

3.19. Paragraph 3.8 of GSR Part 3 [2] states that

> "Any person or organization intending to carry out any of the actions specified in para. 3.5 [of GSR Part 3 [2]][2] shall, unless notification alone is sufficient, apply to the regulatory body for authorization, which shall take the form of either registration or licensing."

3.20. The acceptance that a certain kind of practice is suitable for registration is determined by the regulatory body, which also determines the accompanying conditions (e.g. provision of working procedures, training of personnel, design of the equipment). The exposures, and potential exposures, of the public and the radiological environmental impact from a source that is registered should be inherently small, so that separate investigations or assessments by the registrants for demonstrating safety are not needed.

3.21. Licensing is the most complete and sophisticated form of authorization. In principle, a licence should be required for higher risk or more complex practices, including those for which radiation protection and safety depend significantly or largely on human performance,

3.22. The applicant for an authorization is required by GSR Part 3 [2] to provide the regulatory body with relevant information necessary to support the application, which includes:

(a) An assessment of the nature, likelihood and magnitude of the exposures due to the source in normal operation and a description of all necessary measures for protection and safety;

(b) A safety assessment, as required by the regulatory body;

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[2] Paragraph 3.5 of GSR Part 3 [2] states that

> "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."

(c) An appropriate prospective assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity, as required by the regulatory body.

DS427 [9] provides guidance on how to evaluate exposures and on the use of criteria for the assessment of radiological environmental impact for planned exposure situations.

3.23. A graded approach should be used within licensing that takes into account the expected likelihood and magnitude of the exposures in normal operation and of the potential exposures, the complexity of the practice, and the protection and control measures needed. The graded approach should be reflected in the content and extent of the safety assessment and the assessment for radiological environmental impact. The regulatory body should evaluate the results of the assessments to determine possible additional conditions on which a license can be granted.

3.24. A source within a practice could also cause public exposure outside the territory or other area under the jurisdiction or control of the State in which the source is located. In such situations, the government or regulatory body is required to "ensure that the assessment for radiological impacts includes those impacts outside the territory or other area under the jurisdiction or control of the State; … establish requirements for the control of discharges; [and] … arrange with the affected State the means for the exchange of information and consultations, as appropriate." (para. 3.124 of GSR Part 3 [2])

Justification

3.25. Requirement 10 of GSR Part 3 [2] requires the government or the regulatory body to ensure that only justified practices are authorized. Justification is implemented as a structured process to determine whether the benefits from a practice outweigh the harm (including radiation detriment) to individuals, society and the environment from the practice. This process should be repeated if necessary when there is new information or experience.

3.26. Paragraph 3.17 of GSR Part 3 [2] defines a number of practices that are deemed to be not justified. These are as follows:

(a) Practices, except for justified practices involving medical exposure, that result in an increase in activity, by the deliberate addition of radioactive substances or by activation, in food, feed, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a person;

(b) Practices involving the frivolous use of radiation or radioactive substances in commodities or in consumer products such as toys and personal jewellery or adornments, which result in an increase of activity, by the deliberate addition of radioactive substances or by activation;

(c) Human imaging using radiation that is performed as a form of art or for publicity purposes.

3.27. One consideration in justification is the possibility of alternative methods that do not involve the use of radiation or radioactive material. All alternative methods will have their own costs and benefits. Thus the mere existence of an alternative method should not be used as a reason for deciding that the type of practice involving the use of radiation is not justified. Nevertheless, if such comparisons with 'non-radioactive' alternatives or 'non-radiation-emitting' alternatives are necessary, they should be undertaken with appropriate caution. The methods should be judged on the basis of their effectiveness in accomplishing the intended objective.

3.28. Decisions regarding the justification of a particular type of practice should take account of exposures to all of the relevant categories of exposure (occupational exposures, public exposures), and as appropriate, the assessment of the radiological environmental impact. The decision should include consideration of exposures expected to occur and the possibility of accidents (potential exposures) in operations, decommissioning or waste management. Justification should not be separately applied to one component part of a practice, such as the management of radioactive waste at a nuclear power plant.

3.29. In some States, many of the facilities and activities that produce radiation exposures may not have been subject to a formal justification process. A formal procedure of justification would normally only take place when new techniques are to be authorized for the first time. Nevertheless, the justification for any particular type of practice is required to be subject to review.

3.30. Guidance on the elements that should be considered and the process that should be followed in determining whether the introduction of a particular type of practice is justified is provided in GSG-5 [8].

Optimization of protection and safety

3.31. Requirement 11 of GSR Part 3 [2] states that

"The government or 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."

3.32. Optimization of protection and safety for a planned exposure situation will include both formal reviews as part of the application and authorization process at the design and construction stage, and reviews during operation.

3.33. Optimization of protection and safety can be applied to the components part of a particular practice and can be limited to consideration of the doses to particular groups of people. However, the boundary conditions for any analysis for the purposes of optimization should be carefully chosen since there may be consequences for other component parts of the practice or other groups of people. For instance, the costs and benefits of different effluent treatment options at a nuclear power plant should be considered in the optimization of protection of the public and protection of the environment against exposures due to radioactive discharges to the environment. Some of these options may have significant implications for the way solid wastes are stored at the facility, or for the occupational exposure of workers, which also have to be considered in the optimization process.

3.34. Optimization decisions involve many different factors, and thus may benefit from consideration in a matrix type of approach [23], where the different elements of the matrix, including protection of the public and of the environment, are considerations contributing to the overall decision.

Dose constraints and risk constraints

3.35. Dose constraints should be expressed in terms of effective dose. The dose calculated for comparison with the dose constraint is the sum of the effective dose received in one year from external exposure and the committed effective dose received in this year from internal exposure.

3.36. The dose constraint for a particular source is intended to ensure that the sum of the doses from planned operations for all sources that may contribute to the exposure of the representative person remains within the dose limit. In this respect, possible future practices at the design stage or planning stage should be considered in establishing the dose constraint.

3.37. Dose constraints for public exposure in planned exposure situations are required to be established or approved by the government or the regulatory body (para. 3.120 of GSR Part 3 [2]). The dose constraint can be proposed by the registrant or licensee or operating

organization and be subject to review and approval by the regulatory body. In setting dose constraints, the characteristics of the site and of the facility or activity that are relevant for public exposure, good practices in the operation of similar sources, the dose contribution from other relevant authorized practices, the scenarios for exposure and the views of interested parties should all be considered.

3.38. Dose constraints are should be established in respect of public exposure due to all sources for which an application for authorization is made, for example, for discharges to the environment during normal operation from facilities or activities or for optimizing the shielding in the design of facilities or activities (e.g. a room used for X ray imaging in a hospital or in an industrial radiography facility).

3.39. The value for the dose constraint for public exposure in a planned exposure situation should be below the dose limit for the effective dose of 1 mSv in a year. The dose limit applies to the total dose received by an individual from all sources in planned exposure situations. On the other hand, the value for the dose constraint should be higher than a dose of the order of 10μSv in a year. Therefore, dose constraints should be selected within the range of 0.1 to < 1 mSv in a year.

3.40. The value for the dose constraint should be selected in accordance with the characteristics of the exposure. In establishing the value, the regulatory body should consider the typical number and type of radiation sources in use in the State or region. Some States may establish a generic value for the dose constraint for all sources. However, there may be circumstances that could allow for a specific value for the dose constraint for a particular source to be set by the regulatory body (see para 3.41).

3.41. In establishing the generic value or specific value for the dose constraint, the regional contribution to the exposure of the public from existing or planned practices and other existing or planned practices in the vicinity of the source should be considered. For example, for nuclear installations, other installations on the same site should be assumed to contribute to the exposure of the representative person. In the case of facilities or activities in an urban environment (e.g. hospitals or industrial applications), more than one source could be assumed to contribute to the exposure of the representative person. On the other hand, for facilities or activities located in remote areas, e.g. uranium mine in an extremely remote area, the contribution from other local sources is not likely to be significant, and thus should not be included in the assessment.

3.42. Dose constraints should not be used as dose limits. More specifically, exceeding a dose constraint should not represent a regulatory infraction, as would be the case if a dose limit is exceeded. Given that the dose constraint represents a level of dose for planning measures for protection and safety, if the dose constraint is approached or exceeded in the course of operations, this should result in investigation of the situation, and development of modifications or follow-up actions that may be necessary.

3.43. The risk constraint is a source related value that provides a basic level of protection for the individuals most at risk from a source. This risk is a function of the probability of an unintended event causing a dose and the probability of the detriment due to such a dose. Risk constraints correspond to dose constraints but apply to potential exposure [2].

3.44. Potential exposure of the public includes events resulting in an unplanned release of radioactive material to the environment (e.g. a major accident at a nuclear facility or the malicious use of radioactive material); events resulting in the loss of control of a radiation source; or events in which potential exposures could occur far into the future and doses would be delivered over long time periods (e.g. disposal facilities for radioactive waste after their closure) [5].

3.45. Paragraph 266 of ICRP Publication 103 [5] states that

> "The evaluation of potential exposures, for the purpose of planning or judging protection measures, is usually based on: a) the construction of scenarios which are intended to represent the sequence of events leading to the exposures; b) the assessment of the probabilities of each of these sequences; c) the assessment of the resulting dose; d) the evaluation of the detriment associated with that dose; e) comparison of the results with some criterion of acceptability [e.g. risk constraint]; and f) optimisation of protection which may require several iterations of the previous steps."

3.46. Risk constraints for public exposure are required to be set by the government or the regulatory body [2]. In setting risk constraints, the characteristics of the source and of the practice, good practice in the operation of similar sources, and the views of interested parties are required to be considered [2]. The government or regulatory body should also take into account the prevailing legal, economic and social conditions in establishing risk constraints.

3.47. The ICRP recommends that risk constraints for potential exposures should equate to a similar level of health risk to that implied by the corresponding dose constraints used for normal operation of the same source [5, 20]. However, there can be large uncertainties in

estimating the probability of an unintended event causing exposure. It is often sufficient to use a generic value for a risk constraint.

3.48. DS427 [9] presents a general framework for assessing radiological impacts to the public and for the protection of the environment, which describes the estimation of risk and the use of risk constraints for planned exposure situations.

Dose limits

3.49. Requirement 12 of GSR Part 3 [2] states that

> "The government or the regulatory body shall establish dose limits for public exposure in planned exposure situations, and registrants and licensees shall apply these limits."

3.50. The dose limits for the public are set out in Schedule III of GSR Part 3 [2]. The dose limits for public exposure are:

(a) An effective dose of 1 mSv in a year;

(b) In special circumstances[3], 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.

3.51. Although averaging of effective dose over a five year period is permitted in GSR Part 3 [2], this flexibility is generally not needed in the control of public exposure in planned exposure situations. Furthermore, it is not a straightforward matter to apply such averaging, since the dose limits for public exposure are more hypothetical in nature than they are in the case of occupational exposure, where doses to specific individuals are directly assessed. Thus, a regulatory body should allow flexibility only upon application by a licensee, so that the specific circumstances can be properly addressed. If averaging is used, this should not be done retrospectively of the date of implementation of the requirements of GSR Part 3 [2].

3.52. Dose limits are individual related restrictions and apply to the total dose received by an individual from all relevant sources in planned exposure situations. The calculation of the

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

dose for purposes of comparison with the dose limit should not include the dose due to the natural background levels of radiation. Paragraph 3.27 of GSR Part 3 [2] states that

> "The government or the regulatory body shall determine what additional restrictions, if any, are required to be complied with by registrants and licensees to ensure that the dose limits … are not exceeded owing to possible combinations of doses from exposures due to different authorized practices".

3.53. The effective dose received by members of the public depends upon a number of factors, such as the behaviour of radionuclides in the environment and their transfer to people, the duration and rate of exposure and other relevant factors. These factors cause a wide variation in the effective dose among the exposed population. For the purpose of verifying compliance with the annual dose limit for public exposure, the dose to members of the public should be estimated for the representative person. All members of the public are considered to be adequately protected if the estimated effective dose to the representative person complies with the dose limit. The ICRP indicates that the dose to the representative person "is the equivalent of, and replaces, the mean dose in the 'critical' group" [23].

3.54. According to Requirement 14 of GSR Part 3 [2] "Registrants and licensees and employers shall conduct monitoring to verify compliance with the requirements for protection and safety". Such monitoring should provide sufficient information to determine whether the levels of public exposures comply with the dose limits and to demonstrate that protection and safety is optimized.

EMERGENCY EXPOSURE SITUATIONS

Introduction

3.55. The requirements in GSR Part 7 [4] and in Section 4 of GSR Part 3 [2] for emergency exposure situations apply for preparedness and response for a nuclear or radiological emergency. These requirements include those relating to the transition from an emergency exposure situation to an existing exposure situation (Requirement 18 of GSR Part 7 [4] and Requirement 46 of GSR Part 3 [2]).

3.56. Requirement 4 of GSR Part 7 [4] requires governments to ensure that a hazard assessment is performed to provide a basis for a graded approach in emergency preparedness and response. In the hazard assessment, facilities and activities, on-site areas, off-site areas and locations are required to be identified where an emergency could warrant taking protective and other response actions, with account taken of the uncertainties in, and

limitations of, the information available at the preparedness stage. Paragraph 4.19 of GSR Part 7 [4] introduces five emergency preparedness categories that establish the basis for developing generically justified and optimized arrangements for preparedness for and response to a nuclear or radiological emergency.

3.57. Paragraph 4.27 of GSR Part 7 [4] states that

> "The government shall ensure that, on the basis of the hazards identified and the potential consequences of a nuclear or radiological emergency, protection strategies are developed, justified and optimized at the preparedness stage for taking protective and other response actions effectively in a nuclear or radiological emergency to achieve the goals of emergency response."

3.58. In the protection strategy for an emergency exposure situation, in order to ensure that the goals of emergency response are achieved, different actions should be considered for regaining control over the source and/or preventing exposure via all possible pathways of exposure and/or on the individuals who may be exposed, with account taken of the time necessary for the effective implementation of these actions. For example, in order to prevent or reduce the release of radioactive material following an accident, mitigatory actions could be taken at the source. However, if it is no longer possible to control the source or to prevent a release, actions will have to be taken in respect of the pathways or in respect of those individuals who may be exposed. In such cases, both urgent protective actions and early protective actions and other response actions are warranted, such as evacuation, sheltering, iodine thyroid blocking, relocation, and restrictions on food, milk, drinking water and other commodities.

3.59. The protection strategy and overall emergency arrangements developed in accordance with GSR Part 7 [4] should provide for the safe and effective implementation of the emergency response, particularly during the urgent phase and the early phase of a nuclear or radiological emergency, when very little information is available. However, as the emergency evolves, such as during the transition phase, more information on the circumstances surrounding the emergency and its consequences will become available.

3.60. In the light of increased understanding on the emergency situation as it evolves, the effectiveness of actions and the overall strategy taken early in the emergency response are required to be assessed and adjusted on the basis of the prevailing conditions and the available

information on the emergency. Further justified and optimized strategies should then be considered and implemented as necessary (para. 4.31 of GSR Part 7 [4]).

Goals of emergency response

3.61. Paragraph 3.2 of GSR Part 7 [4] lists the goals of emergency response as follows:

(a) To regain control of the situation and to mitigate consequences;
(b) To save lives;
(c) To avoid or to minimize severe deterministic effects;
(d) To render first aid, to provide critical medical treatment and to manage the treatment of radiation injuries;
(e) To reduce the risk of stochastic effects;
(f) To keep the public informed and to maintain public trust;
(g) To mitigate, to the extent practicable, non-radiological consequences;
(h) To protect, to the extent practicable, property and the environment;
(i) To prepare, to the extent practicable, for the resumption of normal social and economic activity.

These goals should guide the development of protection strategy and of overall emergency arrangements for preparedness and response for a nuclear or radiological emergency in order to ensure an effective emergency response.

Justification

3.62. Requirement 44 of GSR Part 3 [2] and Requirement 5 of GSR Part 7 [4] state that the protection strategies are required to be justified at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency.

3.63. As stated in para. 4.29 of GSR Part 7 [4], the requirement for justification applies for each protective action, in the context of the protection strategy, and for the protection strategy itself. Protective actions taken in an emergency can be disruptive and have adverse psychological or societal consequences (particularly for those individuals evacuated or relocated) as well as major economic and environmental impacts in the affected areas. In addition, the absence of adequate preparedness can result in the taking of actions that are not warranted in the belief that they provide for the protection and safety of individuals affected, but which cause more harm than good. Therefore, it is required to demonstrate that the protective actions and the overall protection strategy do more good than harm, with account taken not only of those detriments that are associated with radiation exposure of individuals

but also of those detriments associated with impacts of the actions taken on public health, the economy, society and the environment.

3.64. Paragraph 4.30 of GSR Part 7 [4] states that

> "The government shall ensure that interested parties are involved and consulted, as appropriate, in the development of the protection strategy."

In the context of an emergency, interested parties should be consulted throughout the process of justification of the overall protection strategy and any protective action in the context of the protection strategy.

3.65. During the urgent phase and the early phase of an emergency, there may be no time to consult interested parties or to consider justification of protective actions and the protection strategy; therefore adequate preparedness needs to account for this. As the emergency response moves towards the transition phase and to remediation activities, there is time to consult interested parties and to address justification. In this phase, more thorough justification of the strategies to enable the termination of the emergency should be implemented. In this context, para. 5.98 of GSR Part 7 [4] requires: "Both radiological consequences and non-radiological consequences shall be considered in deciding on the termination of an emergency as well as in the justification and optimization of further protection strategies as necessary."

3.66. GSR Part 7 [4] requires protective actions and other response actions to be discontinued when they are no longer justified. When such decisions are taken, they should be clearly communicated to all interested parties.

Optimization

3.67. Requirement 44 of GSR Part 3 [2] and Requirement 5 of GSR Part 7 [4] set a requirement for the protection strategies to be optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency.

3.68. As indicated in para. 4.60 of GSR Part 7 [4], in the context of an emergency, consultation of interested parties throughout the process of optimization of the overall protection strategy is required to be done at the preparedness stage and the optimized strategy is required to be implemented in the response.

3.69. During the urgent phase and the early phase of an emergency, there may be no time available to dedicate to the optimization process; therefore adequate preparedness needs to account for this. The situation changes as the emergency moves towards recovery activities and the transition phase. At this point, time will allow for more thorough optimization of the strategy to be implemented to enable the termination of the emergency. The extent of optimization at this point would be as at preparedness stage.

3.70. The optimization of protection strategies should ensure that the best protective actions have been taken under the prevailing circumstances, and all that is reasonable and justified has been done to keep exposure as low as reasonably achievable.

Reference levels

3.71. For emergency exposure situations, GSR Part 3 [2] and GSR Part 7 [4] require that a reference level expressed in terms of residual dose be set, typically as an effective dose in the range of 20–100 mSv, acute or annual, that includes dose contributions via all exposure pathways. The residual dose is the dose expected to be incurred after protective actions have been terminated (or after a decision has been taken not to take protective actions) and so is the dose accumulated from the initiation of the event, through a specified period of time. The purpose of a reference level in an emergency exposure situation is to guide the optimization process of protection strategies aimed at reducing the doses to be incurred by individuals and to be a benchmark for a retrospective assessment of the effectiveness of protective actions taken and the protection strategy in an emergency response.

3.72. The reference level is not the only input in the development, justification and optimization of the protection strategies. Paragraph 4.28 of GSR Part 7 [4] indicates the need for using the reference level in this context in conjunction with the goals of emergency response (see para. 3.61) and the specific time frame in which particular goals are to be achieved.

3.73. Although the decision to select a particular value within the proposed band of reference levels remains with national authorities, para. 4.28 of GSR Part 7 [4] explains that such selection will depend on the phase of the emergency, the practicality of reducing or preventing exposures and other factors.

Generic criteria and operational criteria

3.74. In addition to reference levels, national generic criteria are required to be used to indicate the need for taking protective actions and other response actions in an emergency. If

the doses projected or received in an emergency exceed the national generic criteria, protective actions and other response actions, either individually or in combination within the protection strategy, are required to be implemented.

3.75. Appendix II of GSR Part 7 [4] provides a comprehensive set of generic criteria to be considered when developing the justified and optimized protection strategy, including national generic criteria. The protective actions and other response actions associated with these generic criteria are considered to prevent severe deterministic effects, to reduce the risk of stochastic effects, to mitigate the impact of non-radiological consequences by providing a basis for the continuation or the resumption of international trade following an emergency and for enabling a transition to an existing exposure situation. The process for deriving national generic criteria while taking account of these generic criteria should be such that the associated protective actions and other response actions undergo thorough justification and optimization.

3.76. Once an emergency has occurred, protective actions and other response actions should be promptly implemented on the basis of pre-established operational criteria (emergency action levels, operational intervention levels and observables) that derive from the national generic criteria providing a basis to take effective actions, particularly before substantial information on the situation is available.

EXISTING EXPOSURE SITUATIONS

Introduction

3.77. Paragraph 5.1 of GSR Part 3 [2] sets out situations that shall be regarded as existing exposure situations. These include:

a) Exposure due to contamination of areas[4] by residual radioactive material deriving from past activities that were never subject to regulatory control or that were subject to regulatory control but not in accordance with the requirements of GSR Part 3 [2] or from a nuclear or radiological emergency, after an emergency has been declared to be ended;

[4] The term ‘areas’ is used in its broadest sense and can include land and water bodies.

b) Exposure due to commodities, including food, feed, drinking water and construction materials, that incorporate radionuclides deriving from residual radioactive material as stated in para. 3.77(a);

c) Exposure due to ^{222}Rn and to ^{220}Rn and their progeny in dwellings and in other buildings with high occupancy factors for members of the public;

d) Exposure due to radionuclides of natural origin, regardless of activity concentration, in commodities, including food, feed, drinking water, agricultural fertilizer and soil amendments, and construction materials, and residual radioactive material in the environment;

e) Exposure due to any other materials in which the activity concentration of no radionuclide in either the uranium decay chain, the actinium decay chain or the thorium decay chain exceeds 1 Bq/g and the activity concentration of ^{40}K does not exceed 10 Bq/g;

3.78. Contamination of areas can also arise from the operation of facilities and activities that are subject to regulatory control under the requirements for planned exposure situations, as a result of authorized activities such as discharges, the management of radioactive waste, and decommissioning. The control of such contamination is through the requirements for planned exposure situations, and not through the requirements for existing exposure situations.

3.79. For existing exposure situations, exposures can be reduced only by either protective action or remedial action on the source, the exposure pathway or the exposed populations. In addition, some potential existing exposure situations warranting such actions may be avoided by design. For example, high levels of radon indoors may be avoided by incorporating appropriate preventive measures for radon into the design of new dwellings. Further guidance on such measures is provided in SSG-32 [15].

3.80. Requirement 47 of GSR Part 3 [2] states that

> "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."

3.81. The government and the regulatory body should take measures to identify and evaluate existing exposure situations, taking into account the types of existing exposure situations mentioned in para. 3.77, on the basis of indication or evidence of public exposures that are of concern from the point of view of radiation protection.

Justification

3.82. Requirement 48 of GSR Part 3 [2] states that

> "The government and the regulatory body or other relevant authority shall ensure that remedial actions and protective actions are justified and that the protection and safety is optimized".

3.83. The protection strategy for a particular existing exposure situation is required to be established in accordance with the principle of justification. Any decisions to implement a remedial action or protective action to reduce the radiation dose to the public, which will always have some disadvantages, should be justified in the sense that they are to do more good than harm.

3.84. The remedial actions or protective actions may include, depending on the type of existing exposure situation and the level of projected doses:

(a) Corrective actions in existing buildings and preventive measures in new buildings to reduce radon levels [15];

(b) Remediation of areas with residual radioactive material [14];

(c) Restrictions on access to contaminated buildings or to areas with residual radioactive material [14];

(d) Restrictions on the use of locally produced feed, food or drinking water [para. 3.98-3.101];

(e) Restrictions on the use of construction materials [15];

(f) Restrictions on the use of agricultural fertilizer and soil amendments.

3.85. The justification process should consider, in addition to radiation exposure, other factors such as societal and ethical aspects, available resources, waste management options, and equity issues. Where public doses are relatively high, the radiation risk may be the most important factor in decision making. However, where exposures are low, other factors may become more important and the justification process should go beyond the scope of radiation protection. This broader decision making process calls for input from other organizations and from interested parties.

Optimization

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3.86. The optimization process for an existing exposure situation is implemented through the protection strategy. The protection strategy should be commensurate with the associated radiation risks and may consist of more than one remedial action or protective action. The remedial actions and protective actions selected depend on their technical feasibility and on cost, societal factors, potential adverse impacts, long-term effectiveness and the concerns of the public. A process should be applied to achieve residual doses to the public that are as low as reasonably achievable below the reference level.

3.87. Paragraph 5.8 of GSR Part 3 [2] states that

> "The regulatory body or other relevant authority and other parties responsible for remedial actions or protective actions shall ensure that the form, scale and duration of such actions are optimized. While this optimization process is intended to provide optimized protection for all individuals subject to exposure, priority shall be given to those groups for whom the dose exceeds the reference level. All reasonable steps shall be taken to prevent doses from remaining above the reference levels."

3.88. The success of the implementation of the protection strategy depends on the support and commitment of the parties involved, including the exposed population. This can be achieved by involving interested parties in the decision making process regarding the development and implementation of remedial actions and protective actions. The levels of public exposure depend also strongly on the living habits, which calls for transparent communication to the members of the public on the possible ways they can reduce their exposure. The involvement of the affected communities in the implementation of the protection strategy through self-help actions can also reduce their exposure, and may make an important contribution to the success of the strategy. The regulatory body or other national authority should provide guidance on how self-help actions can be carried out at the local or individual level. The regulatory body or other national authority should periodically evaluate the effectiveness of such self-help actions to provide support that could further improve the situation. Further guidance on self-help actions in the remediation of contaminated areas is currently in preparation.[5]

3.89. The process of optimization should also consider that some remedial actions, such as clean-up work involving the removal of contaminated soil, may lead to exposure of the remediation workers, as well as generating radioactive waste requiring appropriate actions for

[5] Revision of WS-G-3.1 is in preparation.

its processing and disposal. The collection, treatment, storage and disposal of large volumes of such waste may lead to exposure of the public.

3.90. The selection of the optimized remediation option is required to take into account that some remedial actions could have considerable radiological and non-radiological impacts on the environment, which should be considered within the process of optimization, together with technical, societal and economic factors (para. 5.12 (d) of GSR Part 3 [2]).

Reference levels

3.91. Paragraph 5.4 of GSR Part 3 [2] states that the regulatory body or other relevant authority assigned to establish a protection strategy for an existing exposure situation is required to ensure that it specifies appropriate reference levels. Paragraph 5.8 of GSR Part 3 [2] states that the reference levels are typically in the range 1–20 mSv or other equivalent quantity, the actual value depending on the feasibility of controlling the situation and on experience in managing similar situations in the past.

3.92. For existing exposure situations, the reference level is expressed in terms of effective dose to the representative person, or in terms of activity concentration, with account taken of all possible pathways of exposure. The reference level should be used to guide the optimization of protection such that projected doses greater than the reference level are reduced, and further reductions achieved given the circumstances. GSR Part 3 [2] provides a general framework for establishing reference levels. Table 1 in the Appendix summarizes values of dose constraints and reference levels in terms of effective doses.

3.93. Where activity concentrations of radon are of concern for public health, para. 5.20 of GSR Part 3 [2] requires the government to ensure that an action plan for radon is established, which includes the establishment of an appropriate reference level for ^{222}Rn for dwellings and other buildings with high occupancy factors for members of the public that in general will not exceed an annual average activity concentration due to ^{222}Rn of 300 Bq/m^3. [6] The reference level for exposure indoors due to radon should be selected such that the resulting actions are practicable and manageable. For example, it would be impractical to set a reference level such that corrective actions would be necessary for the majority of existing dwellings. The percentages of dwellings that would require corrective remedial actions under different reference levels should be considered in the choice of an appropriate reference level. SSG-32

[6] On the assumption of an equilibrium factor for ^{222}Rn of 0.4 and an annual occupancy factor of 7 000 hours, the value of 300 Bq/m^3 corresponds to an annual effective dose of the order of 10 mSv.

[15] provides recommendations and guidance on the establishment of a reference level for radon in dwellings and other buildings with high occupancy factors for members of the public, and on protection of members of the public against exposure indoors due to ^{222}Rn.

3.94. Requirement 51 of GSR Part 3 [2] states that "The regulatory body or other relevant authority shall establish reference levels for exposure due to radionuclides in commodities", while para. 5.22 of GSR Part 3 [2] specifies that "The regulatory body or other relevant authority shall establish 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."

3.95. Paragraph 5.8 of RS-G-1.7 [22] states that national and international trade in commodities containing radionuclides with activity concentrations below the values of activity concentration provided in Tables I.2 and I.3 of GSR Part 3 [2] should not be subject to regulatory control for the purposes of radiation protection. The activity concentration values in Table I.2 are for bulk quantities of solid material containing artificial radionuclides and were derived using the dose criteria for exemption as set out in para. 3.9 of this Safety Guide. The activity concentration values for radionuclides of natural origin set out in Table I.3 of GSR Part 3 [2] were selected on the basis of consideration of the upper end of the worldwide distribution of activity concentrations in soil [22].

3.96. Paragraph 5.1 of RS-G-1.7 [22] states that there are some situations (such as the use of some building materials containing natural radionuclides) for which exposures from materials due to radionuclides or natural origin with activity concentrations below those given in Table I.3 of GSR Part 3 [2] would necessitate consideration by the regulatory body for some types of regulatory control.

3.97. The regulatory body or other national authority should establish a process to determine the compliance of building materials containing radionuclides of natural origin with the reference level. SSG-32 [15] provides an example of such a process for a reference level of 1 mSv per year for external exposure to gamma radiation for the protection of members of the public against exposure indoors due to radionuclides in building materials. Factors to be considered include the amenability to control and the possibility of different values in different societal groups.

3.98. The regulatory body or other national authority should establish a process to evaluate the levels of radionuclides in food grown in the State in areas that may be affected by past activities or by a nuclear or radiological emergency, and in food imported into the State that may incorporate radionuclides arising from residual radioactive material deriving from a nuclear or radiological emergency after it has been declared ended. This process should identify radionuclides that may be of concern, and should include a methodology for developing guideline levels of activity concentration for these radionuclides in food, on the basis of the specific reference level for food that does not exceed a value of about 1 mSv established by the regulatory body. While in most instances a reference level of 1 mSv or less is appropriate, there may be special circumstances where consideration of a higher value for the reference level may be appropriate, owing to local societal and economic circumstances.

3.99. In developing the national guidelines, the regulatory body or other national authority should consider the methodology used, and is required to consider the guideline levels for radionuclides contained 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 [24] (para 5.23 of GSR Part 3 [2]). It is noted that the Codex guideline values for activity concentration of radionuclides in food were calculated assuming that 10% of the diet consists of imported food, all of which is contaminated, and assuming an exemption level for interventions of 1 mSv per year.

3.100. The regulatory body or other national authority should establish a process to determine the compliance of drinking water in the State with the guideline levels for drinking water published by the World Health Organization (WHO) [25]. The WHO guideline levels for specific radionuclides are calculated using a generic criterion of 0.1 mSv per year for ingestion.

3.101. The situation may arise where the guideline levels for drinking water are consistently exceeded for one or a combination of radionuclides. The regulatory body or other national authority will then need to make a decision regarding the need to implement protective actions or to place some restriction on the continued use of the water supply for drinking [25]. In such situations, the regulatory body or other national authority should establish a reference level for drinking water that would be applied to those water supplies that contain radionuclides that consistently exceed the guideline levels published by the WHO. The regulatory body or other national authority should provide guidance to the public and to water authorities on the need for protective actions or on the need to place restrictions on the use of

the water supply for drinking. The regulatory body or other national authority will need to take account of the availability of other drinking water supplies, and of the costs of protective actions, such as additional water treatment [25].

3.102. Paragraph 5.9 of GSR Part 3 [2] states that

> "The regulatory body or other relevant authority shall periodically review the reference levels to ensure that they remain appropriate in the light of the prevailing circumstances."

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4. PROTECTION OF THE ENVIRONMENT

4.1. According to the ICRP [5, 6, 7, 26], the aims of environmental protection are to prevent or reduce the frequency of deleterious radiation effects on flora and fauna to a level where they would have a negligible impact on the maintenance of biological diversity, the conservation of species, or the health and status of natural habitats, communities, and ecosystems. The IAEA Safety Fundamentals SF-1 [1] recognizes that the present system of radiation protection generally provides appropriate protection of ecosystems in the human environment from harmful effects of radiation exposure. Paragraph 3.28 of SF-1 states that "The general intent of the measures taken for the purposes of environmental protection has been to protect ecosystems against radiation exposure that would have adverse consequences for populations of a species (as distinct from individual organisms)".

4.2. Paragraph 1.34 of GSR Part 3 [2] states that

> "Radiological impacts in a particular environment constitute only one type of impact and, in most cases, may not be the dominant impacts of a particular facility or activity. Furthermore, the assessment of impacts on the environment needs to be viewed in an integrated manner with other features of the system of protection and safety to establish the requirements applicable to a particular source. Since there are complex interrelations, the approach to the protection of people and the environment is not limited to the prevention of radiological effects on human health and on other species. When establishing regulations, an integrated perspective has to be adopted to ensure the sustainability, now and in the future, of agriculture, forestry, fisheries and tourism, and of the use of natural resources".

In general this is achieved by the appropriate application of the optimization principle [2].

4.3. Some States may consider that the assessment of the protection of members of the public during the operation of facilities or the conduct of activities would be sufficient to demonstrate protection of the environment. This position is based on the assumption that the assessment and control of exposure of humans to radiation, which generally leads to very low and localized increments of radiation levels in air, water, sediments and soil, provides appropriate protection of the other elements in the environment.

4.4. Other States may consider that a specific assessment of the radiological impact on other elements of the environment is required, such as an assessment of the exposure of flora and fauna.

4.5. Paragraph 3.9(e) of GSR Part 3 [2] states that

> "Any person or organization applying for authorization…. Shall, as required by the regulatory body, have an appropriate prospective assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity".

4.6. Requirement 9 and para. 3.15 of GSR Part 3 [2] state the responsibilities of registrants and licensees in planned exposure situations. Paragraph 3.15(d) of GSR Part 3 [2] states that

> "Registrants and licensees…. Shall, for the sources for which they are authorized and for which the regulatory body requires a prospective assessment to be made for radiological environmental impacts…, conduct such an assessment and keep it up to date".

4.7. DS427 [9] provides a framework for the prospective assessment of radiological environmental impact in planned exposure situations, which includes the assessment and control of the impact of radioactive releases during normal operation, on the basis of the scientific knowledge of radiation effects; use of such a framework should not impose an unnecessary burden on registrants and licensees or on the regulatory body. DS427 [9] discusses the aspects to be considered when assessing prospectively the radiological environmental impact for planned exposure situations and provides, in Annex I of DS427 [9], a methodology to assess the radiological impact on flora and fauna on the basis of the ICRP approach for the protection of the environment [7, 26].

4.8. The requirements of GSR Part 3 [2] for a graded approach for the control of exposures also apply to the assessment of radiological environmental impacts. The efforts to assess radiological environmental impact, including protection of flora and fauna if considered necessary, should be commensurate with the radiation risks associated with the particular facility or activity.

4.9. For the management of environmental aspects in existing exposure situations and emergency exposure situations, the impact on the environment should be considered as one of the elements in the process of optimization of protection and safety. It will be of particular importance to give consideration to the impacts on the environment from the protective actions and remedial actions to be taken to reduce the exposure of members of the public, as such impacts may in some cases be irreversible. These impacts should be considered in the

justification and optimization processes of the overall protection strategy, as well as of individual protective actions and remedial actions.

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APPENDIX

DOSE CONSTRAINTS AND REFERENCE LEVELS

I.1. Table 1 summarizes the dose constraints and reference levels for existing exposure situations, planned exposure situations and emergency exposure situations, and for different categories of exposure, as established in GSR Part 3 [2].

TABLE 1. FRAMEWORK FOR SOURCE RELATED DOSE CONSTRAINTS AND REFERENCE LEVELS

Range in which the value for a dose constraint or reference level is set	Category of exposure and type of exposure situation
20 to 100 mSv [a,b,c]	• Reference level for public exposure in an emergency exposure situation.
1 to 20 mSv per year	• Dose constraint for occupational exposure in a planned exposure situation. • Dose constraint for medical exposure of carers and comforters in a planned exposure situation. • Dose constraint for individuals undergoing non-medical human imaging that is conducted by medical personnel using medical radiological equipment in a planned exposure situation. • Reference level for workers in an existing exposure situation. • Reference level for public exposure in specific existing exposure situations, e.g. exposure due to radon in dwellings, areas with residual radioactive material.
Not greater than 1 mSv per year	• Dose constraint for public exposure in planned exposure situations. • Reference level for public exposure in specific existing exposure situations, e.g. exposure due to radionuclides in commodities such as food, drinking water or construction materials.

[a] Acute dose or annual dose.
[b] In exceptional situations, informed volunteer workers may receive doses above this band of values to save lives, to prevent severe deterministic health effects, or to prevent the development of catastrophic conditions.
[c] Situations in which the dose threshold for deterministic effects in relevant organs or tissues could be exceeded always require action.

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