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for protecting people and the environment

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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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CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. The fundamental safety objective given in the Safety Fundamentals 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 the harmful effects of ionizing radiation are presented in the Safety Requirements No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards ~~(GSR Part 3)~~ [2]. The governmental, legal and regulatory framework to be used in the implementation of these requirements is given in the Safety Requirements No GSR Part 1, Governmental, Legal and Regulatory Framework for Safety [3].

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, ~~whether~~ i.e. planned exposure situations, emergency exposure situations or existing exposure situations. 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 and medical exposure [2].

1.4. In recent years, consideration has also been given to the protection of the environment in general of which humans are a part. As noted by the International Commission on Radiological Protection (ICRP) [4, 5], some national regulatory frameworks have already included the need to be able to demonstrate that the environment is protected against the effects of radionuclides in environment, irrespective of any human connection with them. The methods and criteria for radiological assessments are being developed and will continue to evolve.

1.5. This General Safety Guide provides generic guidance on the application of the requirements of the GSR Part 3 [2] 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. This is essential to ensure consistency of approaches that includes an integrated consideration of the radiation protection of members of the public and protection of the environment.

OBJECTIVE

1.6. The objective of this General 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 given in GSR Part 3 [2]. Such guidance is intended to underpin the development of facility and activity specific Safety Guides dealing with this area of protection and, by so doing, ensure a consistent approach.

SCOPE

1.7. This General Safety Guide covers the generic application of the requirements given in the GSR Part 3 [2] that relate to the protection of the environment and protection of members of the public for planned exposure situations and existing exposure situations and in the GSR Part 3 [2] and GSR Part 7 [6] ~~in~~ for emergency exposure situations. It is intended for use by governments, regulatory bodies, registrants and licensees, and persons or organizations designated to deal with emergency exposure and existing exposure situations.

1.8. This General Safety Guide does not deal with the detailed application of the requirements in the GSR Part 3 [2] to specific types of facilities or activities and to specific exposure situations. In this context, separate Safety Standards exist or are under development such as GSG-5 [7], DS427 [8], GSG-2 [9], GS-G-2.1 [10], DS442 [11] and SSG-32 [12].

1.9. Occupational exposure and medical exposure are not considered in this Safety Guide.

STRUCTURE

1.10. Section 2 provides an overview of the basic framework for radiation protection of members of the public and the environment in the planned exposure situations, emergency exposure situations and existing exposure situations. It covers the principles of justification, optimization of protection, including dose and risk constraints and reference levels, as appropriate, and dose limits. Section~~s~~ 3 deals with practical application of the radiation protection framework in each exposure situation. Section 4 provides guidance on meeting the requirement of GSR Part 3 on protection of the environment.

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

INTRODUCTION

2.1. Paragraph 2.15 of GSR Part 3 [2] requires that the scope of applicable governmental and regulatory framework to be specified. The regulatory framework should apply 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 given 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 establishes requirements for each of the three exposure situations — planned exposure situation, emergency exposure situation and existing exposure situation [2]. In addition, in the context of emergency exposure situation, GSR Part 7 [6] 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, and by training. [2]

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 accident or from 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 these exposures can usually be predicted. Both exposures and potential exposures can and should be taken into account at the planning or design stage.

2.5. A closely related term to planned exposure situation is ‘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' [13]. Both terms are used in the 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 not subject to regulatory control or that remains after an emergency exposure situation has been declared ended.

2.8. Exposure to natural sources is in general considered in the GSR Part 3 to be an existing exposure situation. However, 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 or thorium decay chains 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 an existing situation);

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

RADIATION PROTECTION PRINCIPLES

2.9. The three basic principles which underpin radiation protection are justification, optimization of protection and safety, and application of dose limits are expressed in Safety Principles 4, 5, 6 and 10 of the Safety Fundamentals [1]. The first two are source-related and apply to all exposure situations. The third is individual-related and applies in planned

exposure situations only. Requirement 1 of GSR Part 3 requires that those responsible for protection and safety ensure that these principles are applied for all exposure situations.

Justification

2.10. Paragraphs 2.8 and 2.9 of GSR Part 3 state: "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"

"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 that 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. In this context, for emergency exposure situations, when considering the justification of the protection actions and the overall protection strategy, paragraph 4.29 of GSR Part 7 [6] states: "Each protective action, in the context of the protection strategy, and the protection strategy itself shall be justified by being demonstrated to do more good than harm, with account taken not only of those detriments that are associated with radiation exposure but also of those associated with impacts of the actions taken on public health , economy, society and the environment."

2.12. Decisions regarding justification should be taken at a sufficiently high governmental level to integrate all of the considerations that may be related to the benefits and detriments. Thus, while the regulatory body or other national radiation protection authority should be responsible for assessing the radiation detriment, it may not be in the 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, potential exposures ~~is~~ are required also to be considered in the justification decision. But dose is only one of the factors involved in the justification process. Many other factors, well beyond radiation protection considerations will need to be considered in determining justification.

Optimization of protection and safety

2.13. Para 2.10 of the GSR Part 3 states: "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."

'Optimized' in this context means that the process of optimization of protection and safety has been applied and the result of that process has been implemented.

2.14. Optimization of protection and safety is defined as the process of 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.

2.15. The process of optimization should be implemented through an on-going cyclical approach that requires:

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

(b) the identification of possible protective options to keep the exposure as low as reasonably achievable;

(c) the selection of the best option under the prevailing circumstances,

(d) implementation of the selected option;

(e) regular review of the exposure situation to evaluate if the prevailing circumstances require any changes to the protective action.

2.16. For planned exposure situations, Requirement 11 of GSR Part 3 [2] states '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 that registrants and licensees shall ensure that protection and safety is optimized.

2.17. For emergency exposure situations, Requirement 44 of GSR Part 3 [2] and Requirement 5 of GSR Part 7 [6] require that the government ensures that protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively. The protection strategy is implemented safely and effectively in response to an emergency through the implementation of the emergency arrangements.

2.18. 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.

2.19. In each exposure situation, the process of justification and optimization should include consultation with interested parties.

Boundaries for optimization

2.20. Optimization of protection should be regarded as a forward-looking, 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 some set of boundaries on the range of available protection options. These boundaries 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 constraints in the case of planned exposure situations and reference levels in the case of emergency or existing exposure situations.

2.21. Constraint is defined as 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 in defining the range of options in optimization.

2.22. 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.

2.23. 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. Risk constraint should equate to a similar health risk to that implied by the corresponding dose constraints for the same source [4, 14]. However, there can be large uncertainties in estimations of the probability 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.

2.24. 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.

2.25. In an emergency exposure situation or in an existing exposure situation, actual exposures may be above or below the reference level. The reference level should then be used as a benchmark to judge the extent to which protective actions are necessary and to assist in prioritizing their application. Optimization of protection should be applied even if the initial doses are below the defined reference levels, if justified and optimized actions are available to reduce exposures. Further discussion on the application of the reference level in emergency exposure situation as a dosimetric concept additional to generic criteria is given in Section 3.

2.26. Implementation of optimized protection strategies should result in exposure levels below the reference level, and as low as reasonably achievable, as long as these reductions are justified taking into account a range of national factors.

2.27. 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 is presented in Appendix 1.

Dose limits

2.28. Paragraph 2.11 of GSR Part 3 states:

"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".

2.29. Dose limits apply in planned exposure situations only. These dose limits are presented in Section 3.

2.30. The annual effective dose to members of the public is the sum of the effective dose obtained within one year from external exposure and the committed effective dose from incorporated radionuclides within this year. The dose is usually not obtained by individual monitoring as for occupational exposure, but is mainly determined by environmental and discharge measurements, habit data, and modelling. It can be estimated from:

(a) Simulation and prediction of radionuclide levels in effluents from the technical installation or source during the design period;

(b) Effluent and external radiation monitoring during the operational period;

(c) Radioecological modelling (pathway analysis of environmental transport, e.g., from the release of radionuclides and transport through soil to plants to animals to humans).

2.31. External exposures of individuals may occur from radionuclides released from installations and which are present in the air, soil, or water. Doses can be calculated from activity concentrations in the environment or discharges by modelling and computation.

2.32. Internal exposures can occur by inhalation of airborne radionuclides from a cloud, inhalation of re-suspended radionuclides, and by ingestion of contaminated food or water.

2.33. 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 of exposure and other relevant factors. These factors cause a wide variation in the effective dose among the exposed population. The 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". The International Commission on Radiological Protection (ICRP) indicates that the dose to the representative person "is the equivalent of, and replaces, the mean dose in the 'critical group" [15].

2.34. The habits (e.g., consumption of foodstuffs, location, usage of local resources) used to characterize the representative person should be typical habits of a small number of individuals representative of those most highly exposed (now or in the future) but not the extreme habits of a single member of the population. Extreme or unusual habits should not dictate the characteristics of the representative person considered. 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.

2.35. According to requirement 14 of the GSR Part 3 "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 the levels of public exposures and to demonstrate that exposures remain optimized and comply with the dose limits.

The government

2.36. The responsibilities of the government with regard to protection and safety applicable to all three exposure situations are set out in paras 2.13-2.28 of GSR Part 3 in general terms. 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; and (e) ensuring arrangements are in place for the provision of technical services, education and training services.

2.37. The responsibilities of the government or the regulatory body with regard to protection of the public in planned exposures situations are set out in Requirement 29 and in paras 3.118-3.121 and in para 3.124 of GSR Part 3. These requirements include: establishing the responsibilities of registrants, licensees and suppliers that are specific to public exposure; establishing the responsibilities of providers of consumer products; to establish and enforce requirements for optimization of protection and safety, including to establish or approve constraints on dose and risk to be used in the optimization of protection and safety for members of the public; and to establish dose limits for public exposure in planned exposure situations.

2.38. 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 in general terms, and in greater detail in GSR Part 7. Some of the responsibilities of the government include establishment of an integrated and coordinated emergency management system, development of justified and optimized protection strategies at the preparedness stage, and ensuring safe and effective implementation of emergency arrangements in an emergency response in accordance with the protection strategy. In addition to assigning responsibilities to the Government in general terms, GSR Part 3 and GSR Part 7 designate response organizations with specific responsibilities in emergency preparedness and response.

2.39. 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. The government is required to ensure that existing exposure situation 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 and protective actions are justified and that the protection and safety is optimized. The government is required to ensure that provision of 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, licensees and other parties involved in the implementation of remedial and protective actions.

The regulatory body

2.40. 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 [3] and in paras 2.29-2.38 of GSR Part 3 [2]. These responsibilities include establishing requirements for applying the principles of radiation protection, establishing a regulatory system that meets specified requirements, ensuring the application of the requirements for education and training in protection and safety, setting acceptance and performance requirements for protection and safety, and making provision for the establishment and maintenance of records.

2.41. 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 limit for public exposure, for authorization of practices, for establishing and approving authorized limits for discharges; 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; and to authorize the provision to the public of the consumer products.

2.42. 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. These responsibilities include: (a) to ensure that arrangements for preparedness and response to a nuclear or radiological emergency under the responsibility of the operating organization 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 ensure that the on-site emergency arrangements are adequate; and (e) 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."

2.43. 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, 5.5, 5.7-5.9 and in Requirement 51 of GSR Part 3. 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 review the reference levels periodically; and (e) to establish reference levels for exposure due to radionuclides in commodities."

2.44. ~~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. These responsibilities include: (a) to ensure that arrangements for preparedness and response to a nuclear or radiological emergency under the responsibility of the operating organization 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 ensure that the on-site emergency arrangements are adequate; and (e) 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."~~

Registrants and licensees

2.45. Requirement 4 of GSR Part 3 states: "The person or organization responsible for facilities and activities that give rise to radiation risks shall have the prime responsibility for protection and safety".

2.46. Requirement 9 of GSR Part 3 states: "Registrants and licensees shall be responsible for protection and safety in planned exposure situations."

2.47. 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 in a practice.

2.48. 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 the ~~BSS~~GSR Part 3.

2.49. In GSR Part 7 [6], the term 'operating organization' is used in this context. The responsibilities of operating organizations in relation to emergency preparedness and response are set out in GSR Part 7, particularly in paras 4.16-4.17.

GRADED APPROACH

2.50. The requirements of GSR Part 3 [2] establish a graded approach for the control of exposure. In particular, Paragraph 2.12 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."

2.51. Para 2.18 GSR Part 3 [2] states: "The government shall ensure that a graded approach is taken to the regulatory control of radiation exposure, so that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation."

2.52. Para 2.31 GSR Part 3 [2] states: "The regulatory body shall adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation."

2.53. Requirement 4 of GSR Part 7 requires 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.

2.54. Para 5.7 of GSR Part 3 requires that "the government and the regulatory body or other relevant authority ensure that the protection strategy for the management of existing exposure situations is commensurate with the radiation risks associated with the existing exposure situation".

2.55. The application of a graded approach in each exposure situations is discussed further in Section 3.

3. RADIATION PROTECTION OF THE PUBLIC

PLANNED EXPOSURE SITUATIONS

Introduction

3.1. Requirements 3.1 to 3.4 of the ~~BSS~~GSR Part 3 set out the practices and sources within practices that are included in the scope ~~for~~ of planned exposure situations. These practices include (a) the production, supply and transport of radioactive material and 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; (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 or processing of raw materials that involve exposure due to radioactive material; and (g) any other practice as specified by the regulatory body. The sources within practices include facilities that contain radioactive material and facilities that contain radiation generators, and individual sources of radiation.

3.2. With regard to natural sources of radiation, para 3.4 of the ~~BSS~~GSR Part 3 states that such exposure is normally subject to the requirements for existing exposure situations. The requirements for planned exposure situations apply to those natural sources of radiation set out in para 3.4 (a) to (d) of the ~~BSS~~GSR Part 3.

3.3. Public exposures in planned exposure situations arise from:

(a) Liquid and airborne discharges from facilities;

(b) Direct radiation from sources within practices, e.g. from X ray equipment in a medical facility;

(c) Consumer products.

3.4. “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” (~~BSS~~GSR Part 3, para. 3.78).

3.5. Requirement 6 of ~~the BSS~~GSR Part 3 requires a graded approach for the implementation of the requirements in ~~the BSS~~GSR Part 3. It states: “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." Para 3.6 states: "The application of the requirements of [~~the BSS~~GSR Part 3] shall be in accordance with the graded approach and shall also conform to any requirements specified by the regulatory body. Not all the requirements of [~~the BSS~~GSR Part 3] are relevant for every practice or source".

3.6. For sources that are included in the regulatory system, appropriate instruments of implementing radiation protection and safety, based on the graded approach, may include notification and authorization, the latter may be in the form of registration or licensing.

Exemption and clearance

3.7. Within a graded approach to protection and safety, the concept of exemption from some or all regulatory requirements for planned exposure situations can be considered. Only justified practices may be exempted.

3.8. The general criteria for exemption given in Schedule 1 of GSR Part 3 [2] are that:

(a) Radiation risks arising from the practice or a source within a 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

(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 provided that the effective dose expected to be incurred by any individual (para. I-2 of GSR Part 3 [2]:

- is of the order of 10 μSv or less in a year under all reasonably foreseeable circumstances, and
- does not exceed 1 mSv in a year for low probability scenarios.

3.10. Another useful concept for the application of a graded approach is clearance which is defined as the removal of radioactive materials or radioactive objects within authorized practices from any further regulatory control. The general criteria for clearance parallel those for exemption prescribed above (Schedule 1 of the GSR Part 3).

3.11. Based on the criteria for exemption and clearance, Schedule I of the GSR Part 3 presents activity concentrations and activities of moderate amounts of material which may be

exempted (Table I-1), activity concentrations for bulk amounts of solid material which may be exempted and material which can be cleared (Table I-2) without further consideration.

3.12. Para. ~~1~~I-3(c) of GSR Part 3 provides for the exemption of radiation generators type approved by the regulatory body, and para. I-6 for the exemption of some equipment containing radioactive material type approved by the regulatory body which are not otherwise exempted based on their activity (Table I-1~~2~~, Schedule I).

3.13. Schedule I of the GSR Part 3 provides also for the exemption and clearance of materials containing radionuclides of natural origin. Table I-3 establishes activity concentration levels for materials containing natural radionuclides which 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 provides for case by case basis exemption of bulk amounts of materials and para. I-12(c) provides for the clearance of residues for recycling into construction materials or for disposal liable to cause the contamination of drinking water.

3.14. Further guidance on exemption and clearance may be found in Safety Guide RS-G-1.7 [16].

3.15. The criteria for exemption and for clearance have been selected to ensure the protection of the public.

Notification and authorization

3.16. Within a graded approach for protection of the public and the environment, notification to the regulatory body "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". (ref. [2], para. 3.7)

3.17. The exposure and risk contribution of 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 the environment. Decisions regarding the use of notification alone should be based on a generic assessment of safety. The expected doses from notified activities should be low enough that there is no need for further considerations regarding public exposures or investigations or assessments with respect to environmental protection.

3.18. Para. 3.8 of ~~the BSS~~GSR Part 3 requires that: "Any person or organization intending to carry out any of the actions specified in para. 3.5 shall, unless notification alone is sufficient, apply to the regulatory body for authorization, which shall take the form of either registration or licensing."

3.19. The acceptance of a registration for a certain kind of practice is determined by the regulatory body, including the accompanying conditions, e.g. provision of working procedures, training of personnel, design of the equipment etc. The exposures, and potential exposures, of the public and the 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.

3.20. Licensing is the most complete and sophisticated form of authorization.

3.21. The applicant for an authorization is required by ~~the BSS~~GSR Part 3 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 expected exposures due to the source and a description of all necessary measures for protection and safety,
(b) a safety assessment,
(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.

The Safety Guide DS427 [8] provides guidance on how to evaluate exposures and the use of criteria for the assessment of radiological environmental impact for planned exposure situations.

3.22. A graded approach should be used within licensing to account for the differences in expected exposures and potential exposures, complexity of the practice, and protection and control measures needed. This should be reflected in the contents and extent of the safety assessment and the assessment for radiological impact. The regulatory body should evaluate the results of the assessments for determining possible additional conditions on which a license can be granted.

3.23. 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 of the

radiological impacts include 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 ref. [2])

Justification

3.24. 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. Therefore any decision to introduce a new technology or type of practice which would give rise to additional exposure of members of the public or impact on the environment should do more good than harm, i.e. should be justified in advance.

3.25. 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 activation, in involving 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 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.

3.26. One consideration in justification is the possibility of alternatives that do not involve the use of radiation or radioactive material. All alternatives will involve their own costs and benefits. Thus the existence of non-radiological options is not, in itself, sufficient to conclude that a practice is, or is not, justified.

3.27. Decisions regarding the justification of a particular type of practice should take account of exposures to all of the relevant categories of exposure (occupational, medical and public exposures), and as appropriate, assessment of the radiological environmental impact. The decision should include consideration of exposures and the possibility of accidents (potential exposures) from operations, decommissioning, waste management, etc. Justification

should not be separately applied to one component of a practice, such as the management of radioactive waste.

3.28. Many of the facilities and activities which create radiation exposures have been in existence for many years and may not have been the subject of a formal justification process. A formal procedure of justification will normally only take place when new techniques are to be authorized for the first time. Nevertheless, the justification for any particular type of practice should be subject to review. Decisions to consider a practice no longer justified should include thorough consideration of affecting factors in consultation with different interested parties.

3.29. Further 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 the Safety Guide GSG-5 [7].

Optimization of protection and safety

3.30. Requirement 11 of the GSR Part 3 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."

3.31. Optimization of protection 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 the operation. Experience has shown that operational experience, using the fundamental questioning attitude of a strong safety culture, is often effective to further improve protection and safety.

3.32. Optimization of protection can be applied to components of a particular practice and limited to a consideration of the doses to particular groups. However, the choice of the boundaries of any optimization analysis should be carefully chosen since there may be consequences for other components and groups. For instance, the costs and benefits of different effluent treatment options may be considered in the optimization of protection of the public and the environment exposed as a consequence of radioactive discharges to the environment. Some of those options may have significant consequences for the storage or disposal of solid wastes, or for the occupational exposure of workers, which must also be considered so that the overall result can be considered as optimized.

3.33. Optimization decisions involve many different factors, and thus may benefit from consideration in a matrix type of approach, where the different components, including

protection of the public, and protection of the environment, are considerations contributing to the overall decision.

Constraints

3.34. Requirement 29 of ~~the BSS~~GSR Part 3 (para. 3.120), which relates to responsibilities specific to public exposure, states that "the government or regulatory body shall establish or approve constraints on dose and on risk to be used in the optimization of protection and safety for members of the public".

3.35. Constraints are prospective and source-related values of individual dose (dose constraint) or risk (risk constraint) that should be used as boundaries in defining the range of acceptable options in the optimization process in planned exposure situations. The dose constraint is generally expressed in terms of effective dose, and should be summed over all exposure pathways that are predicted to arise.

3.36. The dose constraint for each particular source is intended also to ensure that the sum of doses from planned operations for all sources under control remains within the dose limit. In this respect, also possible future practices should be considered in establishing a dose constraint.

3.37. Dose constraints for public exposure in planned exposure situations are required to be set by the government or the regulatory authority. In setting dose constraints, the characteristics of the site and of the facility or activity, the scenarios for exposure and the views of interested parties should be considered.

3.38. A dose constraint is always related to a certain source which may vary depending on the type of practice. For example, a dose constraint may be established for the public exposure caused by releases to the environment of a certain facility. But similarly, for example, a dose constraint may be established for optimizing the shielding of a room used for X ray imaging in a hospital (x-ray diagnostics) or in an industrial facility (industrial radiography). The value of a dose constraint for public exposure in a planned exposure situation should be below the pertinent dose limit, namely 1 mSv for the effective dose. On the other hand, a dose constraint is likely to be somewhat higher than the level of dose which could be considered for exemption. Therefore, dose constraints are likely to fall within the range of 0.1 – 1 mSv. Where other practices cause public exposures simultaneously, it is likely that the dose constraint would need to be within the lower end of this range in order to ensure that the dose limit is not exceeded.

3.39. Dose constraints should not be used as a dose limit. More specifically, exceeding a dose constraint should not represent a regulatory infraction, as would be the case of the dose limit. Given that the constraint represents a level of dose for planning protection and safety, operating experience that approaches or exceeds the constraint should result in investigation of the situation, and development of modifications or follow-up actions that may be necessary.

3.40. 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]

3.41. Potential exposure of the public includes ~~potential exposure of the public in~~ events resulting in unplanned release of radioactive material to the environment e.g. as a result of a major accident in a nuclear facility or the malicious use of radioactive material; potential exposures resulting from the loss of control of radiation sources; or events in which potential exposures occur far into the future and doses would be delivered over long time periods e.g. in the case of solid waste disposal in solid waste repositories [17].

3.42. The evaluation of potential exposures for the purpose of planning or judging protection measures, is usually based on: the construction of scenarios which are intended to represent the sequence of events leading to the exposures; the assessment of the probabilities of each of these sequences; the assessment of the resulting dose; the evaluation of the detriment associated with that dose; comparison of the results with the risk constraint; and optimization of protection which may require several iterations of the previous steps [ICRP 103, para. 266].

3.43. Risk constraints for public exposure are required to be set by the government or the regulatory ~~authority~~ 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 setting the risk constraint.

3.44. 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 [4, 14]. However, there can be large uncertainties in

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

3.45. DS427 [8] presents a general framework to assess 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 ~~[8]~~.

Dose limits

3.46. Requirement 12 of GSR Part 3 [2] requires ~~that~~ "the government or the regulatory body ~~to~~ establish dose limits for public exposure in planned exposure situations, and registrants and licensees are required to apply these limits."

3.47. The dose limits for the public are set out in Schedule III of GSR Part 3. The dose limits for public exposure are:

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

(b) An equivalent dose to the lens of the eye of 15 mSv in a year;

(c) An equivalent dose to the skin of 50 mSv in a year.

3.48. 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 from 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 implementation of GSR Part 3.

3.49. In general, each source of exposure of members of the public will cause a distribution of doses over many individuals. The dose limits for public exposure should therefore be applied to the dose calculated for a representative person. A representative person is defined to be "an individual receiving a dose that is representative of the doses to the more highly exposed individuals in the population". The dose to the representative person is the equivalent of and replaces the mean dose to the critical group.

3.50. Dose limits are individual related and apply to the total dose received by an individual or a representative person from all relevant sources in planned exposure situations. The calculation of the dose should not include the dose due to the local background radiation. In

most situations, one source is likely to dominate and therefore it will normally be sufficient to focus on the dose received from that particular source. Nevertheless, ~~the BSS~~para. 3.27 of GSR Part 3 [2] requires "the government or the regulatory body [to] 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 by possible combinations of exposures from different authorized practices".

EMERGENCY EXPOSURE SITUATIONS

Introduction

3.51. The requirements in GSR Part 7 and in Section 4 of GSR Part 3 for emergency exposure situations apply for preparedness and response for a nuclear or radiological emergency (para. 4.1, Ref. [2] and Ref. [6]). These requirements include those related to the transition from an emergency to an existing exposure situation (see para. 1.4 of Ref. [6] and Req. 46 of Ref. [2]).

3.52. Requirement 4 of the Safety Requirements GSR Part 7 [6]~~,~~ requires for 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 and off-site areas and locations where an emergency could warrant taking protective and other response actions need to be identified with account taken of the uncertainties in and limitations of the information available at the preparedness stage. Para. 4.19 of GSR Part 7 ~~Ref.~~ [6] introduces five emergency preparedness categories which establish the basis for developing generically justified and optimized arrangements for preparedness for and response to a nuclear or radiological emergency.

3.53. On the basis of the hazards identified and the potential consequences of a nuclear or radiological emergency, the governments are required to ensure that 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 [6].

3.54. In the protection strategy for an emergency exposure situation, in order to ensure that the goals of emergency response are achieved, it should be necessary to consider different actions aimed at placing control on the source, on the pathways of exposure and/or on the individuals who may be exposed with account taken of the time allowing 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, there may no longer be possible to control the source or to prevent a release, and actions will be necessary to be taken related to the pathways or to those individuals who may be exposed. In such cases, the protective actions and other response actions are warranted, both urgent and early in the emergency response, and may involve evacuation, sheltering, iodine thyroid blocking, relocation, restrictions on food, milk and drinking water and on other commodities etc.

3.55. The protection strategy and overall emergency arrangements developed in accordance with GSR Part 7 ~~Ref.~~ [6] should provide for a safe and effective implementation of the emergency response particularly during the urgent and early phases 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 circumstance surrounding the emergency and its consequences becomes available.

3.56. 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 should be assessed and adjusted to meet the prevailing conditions and available information in the emergency. Further justified and optimized strategies should be then considered and implemented as necessary (see para. 4.31 of Ref. [6]).

Goals of emergency response

3.57. Para. 3.2 of GSR Part 7 [6] elaborates the goals of emergency response as following: (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; and (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

3.58. Requirement 44 of GSR Part 3 [2] and Requirement 5 of GSR Part 7 [6] set a requirement for the protection strategies to be justified at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency.

3.59. As stated in para. 2.11, the 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 a major psychosocial impact on individuals affected as well as major economic and environmental impacts in the affected areas. In addition, in the absence of adequate preparedness, taking such protective actions can be driven primarily by other factors than radiation protection in the belief that they provide for the safety and protection of individuals affected, and may cause more harm than good. Therefore, the justification of protective actions and the overall protection strategy should demonstrate that these protective actions 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, economy, society and the environment.

3.60. Para. 4.30 of GSR Part 7 [6] states "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, consultation of interested parties throughout the process of justification of the overall protective strategy and any protective action in the context of the strategy should occur.

3.61. During the urgent and early phase, there may be no time to consult interested parties or to consider justification of protective actions and the strategy, therefore adequate preparedness needs to account for this. As the emergency response moves towards recovery activities and the transition phase, there is time for consulting interested parties and for justification. In this phase, more thorough justification of the strategies to enable the termination of the emergency and to transit to the new exposure situation should be implemented. In this context, para. 5.95 of GSR Part 7 states: "Both radiological consequences and non-radiological consequences shall be considered in deciding on the termination of an emergency as well as in justifying and optimizing further protection strategies as necessary."

3.62. GSR Part 7 requires protective actions and other response actions to be discontinued when they are no longer justified.

Optimization

3.63. Requirement 44 of GSR Part 3 [2] and Requirement 5 of GSR Part 7 [6] 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.

3.64. As indicated in para. 3.60, in the context of an emergency, consultation of interested parties throughout the process of optimization of the overall protective strategy should be done at the preparedness stage and the optimized strategy should be implemented in the response.

3.65. During the urgent and early phase, there is no time available to dedicate on the optimization process, therefore adequate preparedness needs to account for this. The situation changes how the emergency is moving towards recovery activities and the transition phase. At this point, the time allows for more thorough optimization of the strategy to be implemented to enable the termination of the emergency and to transit to the new exposure situation. The extent of optimization at this point would be as at preparedness stage. In this context, para. 5.95 of GSR Part 7 states: "Both radiological consequences and non-radiological consequences shall be considered in deciding on the termination of an emergency as well as in justifying and optimizing further protection strategies as necessary."

3.66. The optimization of protection strategies should ensure that the best has been done in the prevailing circumstances, and all that is reasonable and justified has been done to reduce doses.

Reference levels

3.67. For emergency exposure situations, the reference level expressed in terms of residual dose, typically as an effective dose in the range of 20-100 mSv, acute or annual that includes dose contributions from all exposure pathways is proposed [~~1~~2, 6]. The residual dose expresses the accumulated exposure from the initiation of the event, through a specified period of time, taking into account the implementation of the protection strategies (or the absence of such strategies to be implemented). The reference level is a dosimetric concept to guide the optimization process of protection strategies aimed at reducing the doses to be incurred by individuals and a benchmark for a retrospective assessment of effectiveness of actions and strategy taken in an emergency response.

3.68. The reference level is not the only input in the development, justification and optimization of the protection strategies. Para. 4.28 of GSR Part 7 [6] indicates the need for using the reference level in this context together with the goals of emergency response (para. 3.57) and the specific time frame in which particular goals are to be achieved.

3.69. Although the decision to select a value~~s~~ within the proposed band of reference level remains ~~at~~ with national authorities, GSR Part 7 [6] explains that such selection will depend o~~f~~n the phase of the emergency, the practicality of reducing or preventing exposures and other factors.

Generic and operational criteria

3.70. Generic criteria should be used to indicate the need for taking protective actions and other response actions in an emergency. Should the doses projected or received in an emergency exceed the generic criteria, protective actions and other response actions, either individually or in combination within the strategy, should be implemented.

3.71. The Appendix II of GSR Part 7 [6] provides a comprehensive set of generic criteria to be considered when developing the justified and optimized protection strategy including national generic criteria. These generic criteria are considered to be generically justified and optimized to prevent severe deterministic effects, to reduce the risk of stochastic effects and to mitigate the impact of non-radiological consequences (e.g. economic impacts) of an emergency. The process for deriving national generic criteria while taking account of these generic criteria should undergo thorough justification and optimization.

3.72. Once an emergency has occurred, protective actions and other response actions should be promptly implemented on the basis of default operational criteria that derive from the selected generic criteria providing a basis to take effective actions particularly before substantial information is available on the situation.

EXISTING EXPOSURE SITUATIONS

Introduction

3.73. ~~The requirement~~Para. 5.1 of GSR Part 3 sets out situations that shall be regarded as existing exposure situations. These include:

- exposures due to contamination of areas by residual radioactive material deriving from past activities or from a nuclear or radiological emergency after it has been declared ended;
- exposures due to commodities, including food, feed, drinking water and construction materials that incorporate radionuclide arising from residual radioactive material ;
- exposures due to ^{222}Rn and to ^{220}Rn and their progeny in workplaces, in dwellings and in other buildings with high occupancy factors for members of the public;
- exposures due to radionuclides of natural origin in commodities, including food, feed, drinking water, agricultural fertilizer and soil amendments, and construction materials, and ~~existing residues~~residual radioactive material in the environment;
- exposures due to any other materials in which the activity concentration of no radionuclide in either the uranium decay chain or the thorium decay chain exceeds 1 Bq/g and the activity concentration of ^{40}K does not exceed 10 Bq/g;
- exposure of aircrew and space crew to cosmic radiation.

3.74. 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 for an existing exposure situation.

3.75. The requirements for public exposure are required to be applied to workers in existing exposure situations, except for workers undertaking remedial actions in the remediation of areas with residual radioactive material, the exposure of workers due to radon in workplaces and the exposure of aircrew and space crew due to cosmic radiation [2].

3.76. For existing situations, exposures can be reduced only by either protective action or remedial action on the source, exposure pathway or exposed populations. In addition, some existing exposure situations warranting such actions may be avoided by design. For example, high levels of indoor radon may be avoided by incorporating appropriate radon preventive measures into the design of new dwellings. Further guidance on such measures is provided in the Safety Guide SSG-32 [12].

3.77. Requirement 47 of GSR Part 3 requires 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."

3.78. The government and the regulatory body should take measures to identify and evaluate existing exposure situations taking into account ~~of~~the types of existing exposure situations mentioned in para. 3.73~~67~~, based on indication or evidence of public exposures that are of concern from the point of view of radiation protection.

Justification

3.79. Requirement 48 of GSR Part 3 requires 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".

3.80. 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, are to be justified in the sense that they are to do more good than harm.

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

- Corrective actions in existing buildings and preventive measures in new buildings to reduce radon levels.
- Remediation of areas with residual radioactive material.
- Restrictions on access to contaminated buildings or areas with residual radioactive material.
- Restrictions on the use of locally produced foodstuff or drinking water
- Relocation of population.

3.82. The justification process should consider, in addition to radiation exposure, other factors such as: societal and ethical aspects, resources available, waste management options, etc. Where public doses are relatively high, the radiological risk may be the most important factor for decision making. However, where the exposures are lower, other factors will become more important and the justification goes further beyond the scope of radiological

protection. This calls for input from other organizations and interested parties making justification a broad decision process.

Optimization

~~3.83. Requirement 48 of GSR Part 3 requires 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".~~

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

3.85. In paragraph 5.8 of the GSR Part 3 is stated: "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."

3.86. The success of the implementation of the protection strategy depends on the support and commitment of different parties involved, including the exposed population. This can be achieved by involving interested parties in the decision making regarding the development and implementation of remedial 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 influence themselves on the level of exposure they receive.

3.87. The process of optimization should also consider that some remedial actions, such as clean-up work including removal of contaminated soil, may lead to exposures to the remediation workers, as well as, to the generation of waste containing radioactive substances requiring appropriate solutions for ~~their~~ its ~~treatment~~ processing and ~~final~~ disposal. The selection of the optimized remediation protection option should take into account that some remedial actions could have considerable impacts on the environment, which should be

considered within the process of optimization, together with technical, societal and economic factors (paragraph 5.12 (d) of Ref.[2]).[BSS].

3.88. As in the process of justification, the non-radiological aspects will also have an important role in the process of optimization. For example, after an emergency exposure situation, the remaining contamination constituting an existing exposure situation might lead to cycles of remedial measures continuing until no contamination remains. While this may not be necessary on radiation protection grounds and its justification can be questioned, the past experience has shown us that it happens due to different reasons such as political decisions, public pressure etc.

Reference levels

3.89. Para. 1.28 of the GSR Part 3 states that: "The selection of the value for the dose constraint or the reference level would be based on the characteristics of the exposure situation, including:

(i) The nature of the exposure and the practicability of reducing or preventing the exposure;

(ii) The expected benefits of the exposure for individuals and society, or the benefits of avoiding preventive measures or protective actions that would be detrimental to living conditions, as well as other societal criteria relating to the management of the exposure situation;

(iii) National or regional factors, together with a consideration of international guidance and good practice elsewhere."

3.90. For existing exposure situations, the reference level is expressed in terms of effective dose, taking into account all of the possible pathways of exposure. The reference level should be used to guide the optimization of protection such that doses greater than the reference level can be reduced, and further reductions achieved given the circumstances. GSR Part 3 provides a general framework for establishing reference levels. A table summarizing these values is presented in Appendix 1.

3.91. Requirement 50 of the GSR Part 3 requires ~~provides for~~ the establishment of appropriate reference level for ^{222}Rn for dwellings and other buildings~~. It also provides a reference level~~ that is general will not exceed an annual average activity concentration due to ^{222}Rn of 300 Bq/m^3. On the assumption of an equilibrium factor for ^{222}Rn of 0.4 and an annual occupancy factor of 7000 hours, the~~(annual average) as a general reference level for~~

~~this~~ value ~~which equates~~of 300 Bq/m^3 corresponds to an annual~~ized~~ effective dose of the order of 10 mSv. SSG-32 [12] provides recommendations and guidance on regulatory approaches for the protection of members of the public against exposure indoors due to ^{222}Rn.

3.92. Requirement 51 of the GSR Part 3 states: "The regulatory body or other relevant authority shall establish reference levels for exposure due to radionuclides in commodities", and para. 5.22 continues "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."

3.93. Para. 5.23 of the GSR Part 3 states: "The regulatory body or other relevant authority shall consider the guideline levels for radionuclides in food traded internationally that could contain radioactive substances as a result of a nuclear or radiological emergency, which have been published by the Joint Food and Agriculture Organization of the United Nations/World Health Organization Codex Alimentarius Commission ~~[23]~~. The regulatory body or other relevant authority shall consider the guideline levels for radionuclides contained in drinking water that have been published by the World Health Organization ~~[24]~~."

3.94. Para. 5.9 of the GSR Part 3 state 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."

4. PROTECTION OF THE ENVIRONMENT

INTRODUCTION

4.1. GSR Part 3 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" (para. 3.9(e)~~8~~ of ref. [2]).

4.2. Requirement 9 of GSR Part 3 (para. 3.15 of ref. [2]) gives the responsibilities of registrants and licensees in planned exposure situations. It 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".

4.3. Para. 3.123 of GSR Part 3, states that "the regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges. These operational limits and conditions: shall take into account the results of the assessment of the radiological environmental impacts undertaken in accordance with requirements of the regulatory body".

4.4. Requirement 31 of GSR Part 3 covers Radioactive Waste and Discharges[1]. Paragraph 3.132 states among other things that "registrants and licensees, in cooperation with suppliers, in applying for an authorization for discharges, as appropriate: Shall consider the radiological environmental impacts in an integrated manner with features of the system of protection and safety, as required by the regulatory body".

4.5. The IAEA and others have defined principles for protection of the environment. According to ICRP [4, 5, 18] 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. IAEA [2] states that "The general intent of the measures taken for the purposes of environmental

[1] Some aspects of assessment of radiological impact to public and the environment in general are included in Requirement 31 in ~~the BSS~~GSR Part 3 [2~~1~~]. However, the main objective of Requirement 31 is to establish authorized discharge limits. The procedure for establishing authorized discharge limits is not specifically addressed in this Safety Guide and it is discussed more fully in the ~~IAEA's~~ Safety Guide on Discharge Control [11].

protection has been to protect ecosystems against radiation exposure that would have adverse consequences for populations of a species (as distinct from individual organisms)".

4.6. The regulatory body should provide guidance for the prospective assessment for protection of the environment of any proposed facilities and activities.

4.7. One approach is that the assessment for protection to members of the public would be sufficient to demonstrate protection of the wider environment. This position is based on the assumption that the system of protection and safety required for humans generally provides for appropriate protection of the environment from harmful effects of radiation. In that case the assessment may not need to include explicit consideration of the radiation exposures to flora and fauna as described below.

4.8. Another approach is to require the explicit inclusion of additional specific components of the environment, particularly in special situations, e.g. when particular natural resources, endangered species or specially designated protected areas — like nature reserves — are under consideration.

4.9. The explicit assessment of protection of flora and fauna for normal operations will depend on the requirements established in the national regulations, and the characteristics of the activities and facilities under consideration.

THE PROTECTION OF HUMANS AND ENVIRONMENT IN AN INTEGRATED MANNER

4.10. In GSR Part 3 [2], objectives for radiological protection of flora and fauna are defined in accordance with ICRP [4]. However, it is also stressed that radiological protection of the environment should not be considered in isolation since man is an integral part of the environment. GSR Part 3 (para. 1.34) states that "Radiological impacts in a particular environment constitute only one type of impact and, in most cases, may not be the dominant impact 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". Besides the pure radiological protection of people and flora and

fauna, the sustainable use of natural resources for e.g. agriculture, forestry fishery and tourism – now and in the future – should be ensured, which is in general warranted by the appropriate application of the optimization principle [2].

4.11. The integration of humans and environmental protection is mentioned in the introductory part of GSR Part 3 [2]. This integration can be considered in practical terms assuming a linkage in the exposure scenarios. Figure 1 shows a scheme for estimating and evaluating exposures of people and flora and fauna and indicates the link between the exposure scenarios in case of a planned exposure situation. The assessment of exposures to both humans as well as to flora and fauna is based on measured or estimated radionuclide activity concentrations in the environment. Based on this approach the decision making could be based on humans, flora and fauna and environmental resources in an integral manner.

4.12. For the management of environmental aspects during 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 the protection for people. It will be of particular importance to give consideration on the impact on the environment from the protective and remedial actions to be taken to reduce the doses to members of the public as these impacts may be in some cases irreversible. These impacts should be considered in the justification and optimization processes of the overall protection strategy as well as of individual protective and remedial actions.

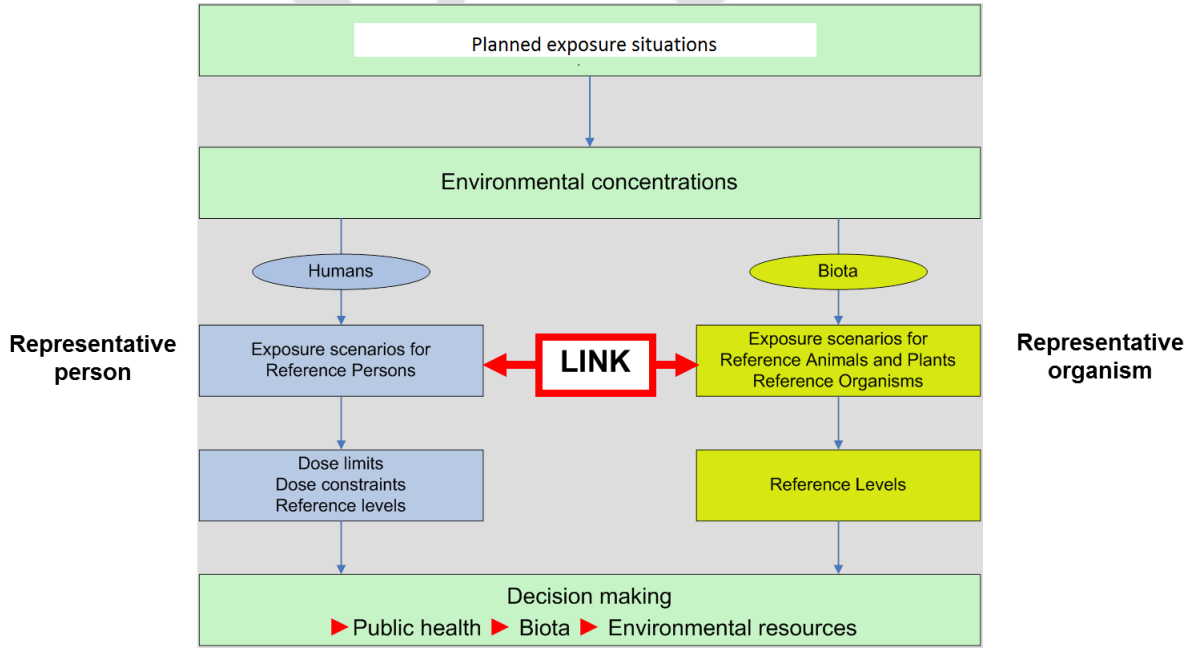

Figure 1: Schematic comparing the process for estimating and evaluating exposures to people and flora and fauna.

4.13. The efforts to assess radiological environmental impact, including estimation of doses to flora and fauna when considered necessary, should be commensurate with the radiation risk related to a particular exposure situation. For planned exposure situations, where radioactive releases are minimized and controlled, the expected radiological impact to the environment, including the resulting doses to flora and fauna, represent low risk at the level of population of species. Therefore, a radiological impact assessment of a generic character should be performed.

4.14. For most facilities and activities, a generic assessment should be sufficient to demonstrate protection of flora and fauna. The Safety Guide DS427 provides a generic approach to assess protection of the flora and fauna [8]. However, a generic approach may not be appropriate for the assessment of the impact to flora and fauna in particular circumstances, for example when dealing with protected species (that, in some cases, if endangered, may be protected at the level of individuals) or when very sensitive ecological niches are identified.

4.15. The regulatory body or other competent governmental agency should identify specific exposure scenarios that require special considerations rather than those of a generic character. The assumptions and types of assessments for situations needing special consideration should be discussed amongst organization responsible for conducting the assessment, the national regulatory body or the competent governmental agency. In any case, the generic methods described in the Safety Guide DS427 [8] could be used as a screening tool for those particular circumstances.

4.16. For planned exposure situations a framework for radiological environmental impact assessment and protection of the public such as that presented in the Safety Guide DS442 [11] should be applied to estimate and control radiological effects on public and effects on the environment.

APPENDIX I

Table I-1 shows the framework of source related dose constraints and reference levels, as established in GSR Part 3 [2].

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

Values for constraints and reference levels	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	• 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 situations ~~e.g. exposure due to radon in workplaces, exposure of aircrew and space crew due to cosmic radiation~~. • Reference level for public exposure in specific existing exposure situations e.g. exposure due to radon in dwellings, areas with residual radioactive material in areas.
Not greater than 1 mSv	• Dose constraint for public exposure in planned exposure situations. • Reference level for the public exposure in specific existing exposure situations e.g. exposure due to radionuclides in commodities such as food, drinking water, construction materials.

[a] Acute or annual dose.
[b] In exceptional situations, informed volunteer workers may receive doses above this band to save lives, prevent severe radiation-induced health effects, or 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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