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Regulatory Control of Radioactive Discharges to the Environment

DRAFT SAFETY GUIDE

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(Revision of WS-G-2.3)

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1. INTRODUCTION

BACKGROUND

1.1. Facilities and activities¹ that give rise to radiation risks are required to be designed, built, authorized, operated and maintained so as to prevent radioactive releases to the environment or to minimize the consequences, providing adequate levels of protection of the public and protection of the environment [3].

1.2. Some facilities and activities generate gaseous and liquid effluents during normal operation that contain small amounts of radionuclides that may expose the public and the environment to low levels of radiation. In many cases, the complete prevention of the release of such effluents is technically difficult or extremely costly to achieve. In all cases, the resulting doses to any member of the public must be below established limits.

1.3. In accordance with the requirements for optimization of radiation protection it can be concluded that, if releases are controlled such that “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)” [3], then such releases may be acceptable with regard to protection and safety, considering the very low radiological significance of the releases and the possibly high costs that may be associated with reducing them further.

1.4. Facilities and activities that generate controllable radioactive releases are regulated in different ways through a graded approach. In many cases, the regulation of facilities and activities generating radioactive releases in normal operation that result in very low doses to the public and for which there is no risk of an unexpected accidental release can be managed through the application of the concept of exemption or by means of notification [3]. However, some releases may result in doses with a higher level of radiological significance or the facility or activity may present potentially higher radiation risks. In such cases it may be appropriate for the regulation of the releases from such facilities or activities to be managed by means of an authorization (registration or licensing, as relevant), which establishes stringent technical and regulatory conditions, including for the adequate management and

¹ The term ‘facilities and activities’ is defined in Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1 [1] and the IAEA Safety Glossary [2]. It is a general term encompassing all nuclear facilities and uses of all sources of ionizing radiation. The recommendations of this Safety Guide apply to certain activities and facilities, as described in para 1.13.

control of these effluents and their radiological consequences. For a practice that is justified, the decision to authorize such releases should take into account the radiation protection principles of optimization and dose limitation, and other relevant safety principles.

1.5. Dose limits and dose constraints are established for the doses received by the public due to the authorized releases of effluents [3]. In accordance with SF-1[1] and the requirements established in Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3 [3] , effluents are required to be properly managed by the licensee, in order to ensure the optimized protection of the public and protection of the environment.

1.6. ‘Discharge’ is the planned and controlled release of gaseous, aerosol or liquid radioactive substances to the environment and, as such, the term does not include releases to the environment in an accident. Strictly, the term discharge refers to the act or process of releasing material to the environment, but it is also used in this Safety Guide to describe the material being released or to be released [2].

1.7. This Safety Guide provides recommendations on the application of the safety requirements established in GSR Part 3 [3] to the regulatory control of discharges and takes account of the recommendations provided in a number of relevant Safety Guides [4-10] and experience of Member States. This Safety Guide supersedes IAEA Safety Standards Series No. WS-G-2.3 on Regulatory Control of Radioactive Discharges to the Environment².

OBJECTIVE

1.8. The objective of this Safety Guide is to provide governments, regulatory bodies, applicants and operating organizations with a structured approach to controlling radiation exposures of the public resulting from discharges from normal operations of facilities and activities, and for the optimization of protection and safety. Guidance is provided on the authorization of discharges, demonstrating compliance with the authorization and enforcing the authorization.

1.9. This Safety Guide is for use by those applying for an authorization for discharges to the environment and by those reviewing applications and authorizing discharges, as part of an authorization process [3]. It may also be relevant for other interested parties.

² INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Control of Radioactive Discharges to the Environment, IAEA Safety Standards Series No. WS-G-2.3, IAEA, Vienna (2000).

SCOPE

1.10. The scope of this Safety Guide is limited to discharges to the atmosphere of airborne effluents and to surface aquatic media of liquid effluents from facilities and activities during normal operation in planned exposure situations [3]. The disposal of solid radioactive waste, releases of radioactive substances in the post-closure period of a waste disposal facility, the migration of liquids containing radionuclides into underground water, and releases to the environment due to accidents are not addressed in this Safety Guide; relevant guidance is provided in other Safety Guides [11 – 14].

1.11. This Safety Guide provides guidance on the regulatory control of discharges in connection with an authorization process³. More specifically, this Safety Guide addresses the authorization of discharges from new and modified facilities or activities, and the review of established authorizations for discharges.

1.12. This Safety Guide addresses the derivation of operational limits and conditions for discharges, the demonstration of compliance with the authorization and the need for a radiation monitoring programme. An important initial input into the process of controlling discharges is the prospective assessment of the protection of the public and the environment from harmful effects of ionizing radiation. A separate Safety Guide provides recommendations on such prospective radiological impact assessments for both protection of the public and protection of the environment [7]. Only limited reference is made in this Safety Guide to the methodology used in dose assessments and the models and data that may be used in the derivation of authorized limits, such as those described in Ref. [15]⁴.

1.13. This Safety Guide applies to different types of facilities and activities that discharge liquid and gaseous effluents containing radionuclides that may give rise to radiation risks to the public. Such facilities and activities range from nuclear installations⁵ to applications of radioisotopes in industry, medicine and research. This Safety Guide also covers the

³ Requirements on the authorization process for facilities and activities, as it relates to the system of protection and safety, are established in GSR Part 3 [3].

⁴ A revision of Safety Reports Series No. 19 [15] is in preparation, and will cover screening assessments of public exposure; generic models and parameters for use in assessing the impact of radioactive discharges; and generic models and parameters for assessing exposures of flora and fauna due to radioactive discharges from facilities and activities.

⁵ The term ‘nuclear installation’ includes: nuclear power plants; research reactors (including subcritical and critical assemblies) and any adjoining radioisotope production facilities; spent fuel storage facilities; facilities for the enrichment of uranium; nuclear fuel fabrication facilities; conversion facilities; facilities for the reprocessing of spent fuel; facilities for the predisposal management of radioactive waste arising from nuclear fuel cycle facilities; and nuclear fuel cycle related research and development facilities [3].

controllable releases in normal operation to the atmosphere and to surface waters that may result from the mining and processing of ores for the extraction of uranium or thorium as part of the nuclear fuel cycle. Consideration is also given to discharges of naturally occurring radioactive material⁶ in non-nuclear industries.

1.14. This Safety Guide focuses on setting discharge limits for protection of the public; radiation protection of workers is considered only as part of the optimization of the protection and safety, especially in connection with the on-site management of radioactive waste and effluents. Recommendations on the assessment and control of occupational exposures are provided in Occupational Radiation Protection, IAEA Safety Standards Series No. DS453 [16]

STRUCTURE

1.15. Section 2 sets out the principles of radiation protection applicable to the control of discharges. Section 3 presents the safety objectives, requirements and concepts relevant to the control of discharges, including the general responsibilities of the government, the regulatory body, the operating organization and other relevant parties. Section 4 provides guidance on the decision process for establishing the need for an authorization for discharges. Section 5 provides recommendations on the process for authorization of discharges, including the development of an authorization for discharges and the setting of discharge limits, the establishment and use of dose constraints, the characterization of discharges and the exposure scenarios used for specifying discharge limits, the consideration of optimization of protection and safety, the assessment of doses to the public, the operational limits and conditions associated with the authorization, the demonstration of compliance, and the involvement of interested parties. Section 6 covers discharges of naturally occurring radionuclides. In Section 7, the aspects relating to the control of discharges during decommissioning are presented. Finally, Section 8 provides recommendations on the regulation of discharges from previously unregulated practices. Annex I provides practical considerations that can be taken into account when setting authorizations for discharges.

⁶ Naturally occurring radioactive material (NORM) is radioactive material containing no significant amounts of radionuclides other than naturally occurring radionuclides [3].

2. THE PRINCIPLES OF RADIATION PROTECTION FOR CONTROL OF DISCHARGES

2.1. The radiation protection and safety principles established in the IAEA Safety Standards [1, 3], on the basis of the recommendations of the ICRP [17], relevant for the control of radioactive discharges to the environment from a facility or activity in planned exposure situations are the principles of justification, optimization and dose limitation.

JUSTIFICATION OF FACILITIES AND ACTIVITIES

2.2. For authorization of a facility or activity, it is required to be demonstrated that the introduction of that practice will produce a positive net benefit, i.e. the expected benefits to individuals and to society from the practice outweigh the harm, including radiation detriment [3]. 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 taken into account [6]. Any decision on justification should always involve consideration of the radiation doses expected either to be incurred, or to be averted or reduced, according to the circumstances. The radiation dose to the public 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 whether a practice is justified.

2.3. Justification applies to the overall practice and not to individual aspects of the practice, such as discharges, which can only be authorized, or exempted from the requirement for an authorization, if the practice as a whole is already regarded as justified.

OPTIMIZATION OF PROTECTION

2.4. The principle of optimization of protection and safety should be applied when setting discharge limits. Optimization of protection and safety is defined as “the process of determining the level of protection and safety required to keep the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure as low as reasonably achievable, economic and social factors being taken into account” (ALARA) [3].

2.5. The protection and safety measures should provide the highest level of safety that can reasonably be achieved throughout the lifetime of the facility or activity without unduly limiting the operation of the facility or activity. The optimization of protection and safety involves the balancing of all costs, not just financial costs, associated with achieving a

particular level of protection and safety, against the benefit in terms of reduction in dose. Further guidance on the optimization process relating to the control of discharges is provided in Section 5 and additional information is provided in Annex I of this Safety Guide

APPLICATION OF DOSE LIMITS

2.6. For planned exposures situations, exposures and risks are subject to control to ensure that the specified dose limits are not exceeded, and optimization is applied to attain the desired level of protection and safety [3].

2.7. The dose limits that are relevant for members of the public in connection with discharges during normal operation are [3]:

- (a) An effective dose of 1 mSv in a year;
- (b) In special circumstances⁷, 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.

These dose limits represent the maximum acceptable dose to any member of the public from all authorized radiation sources to which he or she is exposed in planned exposures situations⁸. The use of dose limits to set discharge limits for a specific source is described in Section 5 and Annex I.

⁷ For example, in authorized, justified and planned operating conditions that lead to transitory increases in exposures.

⁸ GSR Part 3 [3] also establishes dose limits for the public for the equivalent dose to the lens of the eye and to the skin. Because of the conditions in which such exposures would occur, these dose limits are not relevant for discharges to the environment during normal operation.

3. SAFETY OBJECTIVES AND REQUIREMENTS RELEVANT TO THE CONTROL OF RADIOACTIVE DISCHARGES

GENERAL

3.1. The Fundamental Safety Principles [1] establishes principles to be applied to achieve the fundamental safety objective of protecting the public and the environment, now and in the future, from harmful effects of ionizing radiation. This safety objective has to be achieved without unduly limiting the operation of facilities and the conduct of activities that give rise to radiation risks.

3.2. The requirements for a governmental, legal and regulatory framework for safety are established in Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev.1) [18].

3.3. GSR Part 3 [3] describes the concepts and establishes requirements for the protection of people and protection of the environment from harmful effects of ionizing radiation and for the safety of radiation sources. It also establishes requirements, relevant to the various interested parties (e.g. the government, the regulatory body and the operating organization), for the control of discharges.

3.4. GSR Part 3 [3] specifies the system of protection and safety that aims “to assess, manage and control exposure to radiation so that radiation risks, including risks of health effects and risks to the environment, are reduced to the extent reasonably achievable” [3]. For planned exposure situations, GSR Part 3 [3] states that “exposures and risks are subject to control to ensure that the specified dose limits for public exposure are not exceeded, and optimization is applied to attain the desired level of protection and safety” [3].

3.5. Although the system of protection and safety required by the IAEA Safety Standards is founded primarily on considerations of the radiation protection of humans, it also aims to provide for appropriate protection of the environment from harmful effects of ionizing radiation [3].

3.6. The establishment of discharge limits for facilities and activities, as described in this Safety Guide, is primarily for optimization of the protection of members of the public (i.e. the objective of the assessment to determine discharge limits is control of the effective dose to the

representative person⁹, with appropriate consideration given to radiation protection of workers at the discharging facility. This approach is based on the conclusion that the environment is protected by means of the conditions under which the practice is authorized¹⁰.

JUSTIFICATION

3.7. Paragraph 2.8 of GSR Part 3 [3] 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”.

3.8. Requirement 10 of GSR Part 3 [3] states that “The government or the regulatory body shall ensure that only justified practices are authorized”.

OPTIMIZATION OF PROTECTION AND SAFETY

3.9. Requirement 31 of GSR Part 3 [3] on radioactive waste and discharges states that “Relevant parties shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the authorization”.

3.10. GSR Part 3 [3] establishes a number of requirements for the management of radioactive waste, notably including the requirement to ensure that “radioactive waste generated is kept to the minimum practicable in terms of both activity and volume”. The need to meet these requirements on waste management will have a direct impact on the volume of the waste generated and the amount of radionuclides in the waste and in the effluents resulting from the normal operation of a facility or conduct of an activity.

3.11. Paragraph 3.119 of GSR Part 3 [3] specifies that “The government or the regulatory body shall establish and enforce requirements for the optimization of protection and safety for

⁹ The representative person is defined for the purposes of radiation protection as “an individual receiving a dose that is representative of the more highly exposed individuals in the population” [3]. The representative person will generally be a hypothetical construct and not an actual member of the population. The representative person can be considered to be the same concept as the critical group, and similar methods can be used for assessing doses to the representative person to those methods used previously for assessing doses to the critical group [14, 16].

¹⁰ Some States consider that, in addition to the optimization of the protection of the public, there may be a need to assess and verify more explicitly the protection of the environment, including, for instance, estimating the impact of radiation exposure on populations of flora and fauna. DS427 [7] provides guidance on prospective radiological environmental impact assessment that includes, as an example in an annex, a methodology for assessing exposures of flora and fauna and the relevant criteria. Usually, explicit consideration of the exposure of flora and fauna will not influence the setting of discharge limits.

situations in which individuals are or could be subject to public exposure”. Paragraph 3.120 of GSR Part 3 [3] states that “The government or the regulatory body shall establish or approve constraints on dose and constraints on risk to be used in the optimization of protection and safety for members of the public”.

3.12. Paragraph 3.22 of the GSR Part 3 [3] states that “The government or the regulatory body ... shall establish or approve constraints on dose... or shall establish or approve a process for establishing such constraints, to be used in the context of optimization of protection and safety”.

3.13. Requirement 11 of GSR Part 3 [3] 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”.

3.14. Paragraph 3.126 of GSR Part 3 [3] specifies that the following are required to be taken into account in applying the principle of optimization of protection and safety in relation to public exposure:

- (a) “Possible changes in any conditions that could affect exposure of members of the public, such as changes in the characteristics and use of the source, changes in environmental dispersion conditions, changes in exposure pathways or changes in values of parameters used for the determination of the representative person;
- (b) Good practice in the operation of similar sources or the conduct of similar practices;
- (c) Possible buildup and accumulation in the environment of radioactive substances from discharges during the lifetime of the source;
- (d) Uncertainties in the assessment of doses, especially uncertainties in contributions to doses if the source and the representative person are separated in space or in time”.

AUTHORIZATION

3.15. Paragraph 3.132 in GSR Part 3 [3] establishes requirements regarding discharges that underpin the recommendations provided in this Safety Guide. It states that “Registrants and licensees, in cooperation with suppliers, in applying for an authorization for discharges, as appropriate:

- (a) Shall determine the characteristics and activity of the material to be discharged, and the possible points and methods of discharge;

- (b) Shall determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public;
- (c) Shall assess the doses to the representative person due to the planned discharges;
- (d) 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;
- (e) Shall submit to the regulatory body the findings of (a) - (d) above as an input to the establishment by the regulatory body, in accordance with para. 3.123, of authorized limits on discharges and conditions for their implementation”.

3.16. Paragraph 3.123 of GSR Part 3 [3] establishes the following requirements relating to the control of discharges: “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:

- (a) Shall be used by registrants and licensees as the criteria for demonstration of compliance after the commencement of operation of a source;
- (b) Shall correspond to doses below the dose limits with account taken of the results of optimization of protection and safety;
- (c) Shall reflect good practice in the operation of similar facilities or activities;
- (d) Shall allow for operational flexibility;
- (e) Shall take into account the results of the assessment of the prospective assessment for radiological environmental impacts that is undertaken in accordance with national requirements of the regulatory body”.

DOSE LIMITATION

3.17. Requirement 12 of GSR Part 3 [3] states that “The government or the regulatory body shall establish dose limits for ... public exposure, and registrants and licensees shall apply these limits”. Paragraph 3.26 of GSR Part 3 [3] goes on to state that “The regulatory body shall enforce compliance with the dose limits ... for public exposures in planned exposure situations”.

TRANSBOUNDARY IMPACTS

3.18. Paragraph 3.124 of GSR Part 3 [3] establishes requirements for the assessment for radiological impacts and the control of discharges when a source within a practice could cause

public exposure outside the territory or other area under the jurisdiction of control of the State in which the source is located. In such situations, “the government or the regulatory body

(a) Shall ensure that the assessment for radiological impacts includes those impacts outside the national territory or other territory under the jurisdiction of control of the State;....

(c) Shall arrange with the affected States the means for the exchange of information and consultations, as appropriate.”[better to quote rather than paraphrase]

PERIODIC REVIEW

3.19. Paragraph 3.134 of GSR Part 3 [3] establishes requirements for registrants and licensees (operating organizations) to “review and modify their discharge control measures... taking into account:

(a) Operating experience [e.g. changes in the characteristics of the source term];

(b) Any changes in exposure pathways or in the characteristics of the representative person that could affect the assessment of doses due to the discharges”.

SOURCE MONITORING AND ENVIRONMENTAL MONITORING

3.20. Requirement 32 and para. 3.135 of GSR Part 3 [3] require the regulatory body and relevant parties to ensure that programmes for source monitoring and environmental monitoring are in place¹¹. The programmes are required to be sufficient to verify compliance with the requirements for the control of public exposures. These requirements include “Making provision for maintaining records of discharges, results of monitoring programmes and results of assessments of public exposure”. Similar requirements are also placed on registrants and licensees (operating organizations) including the requirement to “Verify the adequacy of the assumptions made for the assessment of public exposure and the assessment for radiological environmental impacts” (para 3.137, GSR Part 3 [3]).

3.21. Registrants and licensees (operating organizations) are required by para. 3.137 of GSR Part 3 [3] to “Establish and implement monitoring programmes to ensure that public exposure due to sources under their responsibility is adequately assessed and that the assessment is sufficient to verify and demonstrate compliance with the authorization”.

¹¹ Guidance on source monitoring and environmental monitoring for use in defining the monitoring programmes relating to public exposure control is provided in Environmental and Source Monitoring for Purposes of Radiation Protection, IAEA Safety Standards Series No. RS-G-1.8 [9].

GRADED APPROACH

3.22. The specific requirements relating to a graded approach are established in GSR Part 1 (Rev. 1) [18], GSR Part 3 [3] and GSR Part 4 (Rev. 1) [19]. In relation to the control of discharges, the graded approach should be reflected in the application of Requirement 6 of GSR Part 3 [3] for planned exposure situations, i.e. the resources devoted to assessing and controlling discharges and the scope and stringency of the regulations are required to be commensurate with the magnitude of the radiation risk and the extent to which the exposure is amenable to control.

4. ESTABLISHING THE NEED FOR AN AUTHORIZATION FOR DISCHARGES

4.1. Figure 1 illustrates a scheme for deciding whether an authorization for discharges is necessary. Radioactive discharges can be considered for authorization only if the overall practice is justified. In order to decide whether an authorization for discharges is necessary, a key factor is whether the exposures due to the discharges are excluded from regulatory control or the discharges can be exempted from the requirement for an authorization.

4.2. Authorization for discharges is not necessary for practices that are excluded from regulatory control because they result in exposures of the public that are deemed to be not amenable to control, or for situations where the criteria for exemption are fulfilled. The regulatory body should specify when the radiation exposures due to discharges are excluded from regulatory control¹², or when the discharges are exempted from the requirement for an authorization, in accordance with the definitions and the criteria established in Schedule I of GSR Part 3 [3]¹³.

¹² The regulatory body should consider, on the basis of the actual characteristics of the radiological impact on public, whether those practices that have historically been excluded from regulatory control should indeed be incorporated into the regulatory system.

¹³ Schedule I in GSR Part 3 [3] also provides information on levels of activity and activity concentration for a large number of radionuclides to assist with determining whether moderate amounts of materials and bulk amounts of solid materials can be exempted from the requirements. However, those levels are not intended for and should not be applied to the control of discharges. Further information is provided in Application of the Concepts of Exclusion, Exemption and Clearance, IAEA Safety Standards Series No. RS-G-1.7 [20].

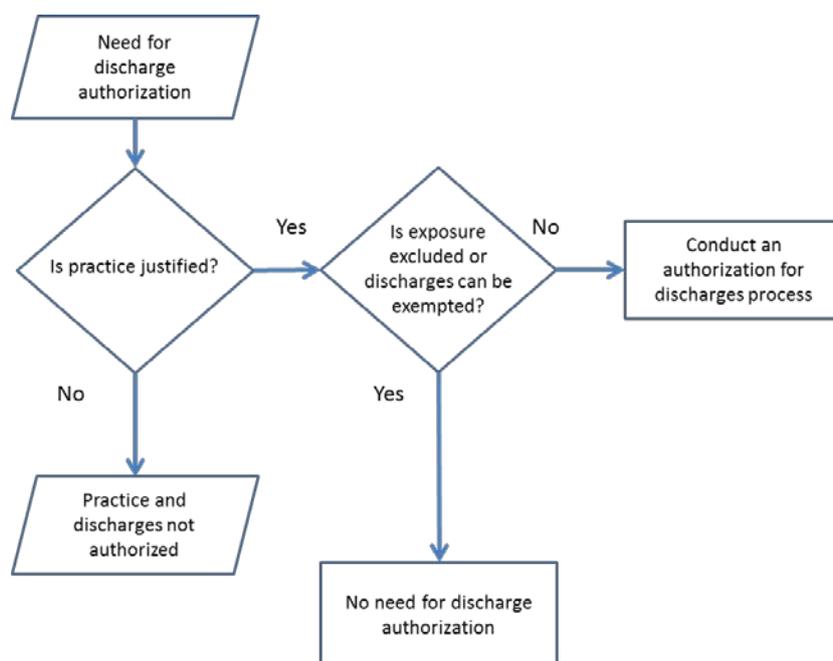


FIG. 1. Flow chart depicting a decision process to determine the need for an authorization for discharges.

4.3. Exemption from the requirement for an authorization for discharges may be granted generically for certain types of practice (e.g. certain uses of short lived radionuclides in medicine for diagnosis or as radiotracers in small research laboratories) or on a case by case basis. If exemption is to be granted generically, the regulatory body should specify the conditions under which the exemption of discharges is warranted for the particular practice. Exemption is a decision made within the regulatory system and the provisions for exemption may be amended by the regulatory body. In cases where exemption is granted, no authorization for discharges is necessary and the regulatory body may decide to verify by simple checks that the conditions for granting exemption to the discharges still apply, for example, from records on acquisitions of radionuclides that permit the activity released to the environment to be estimated.

4.4. In some cases, the regulatory body could decide that a practice and the associated discharges need only notification (and not authorization). Notification alone should be used only when the doses to the public expected from normal operation are low (e.g. a small fraction of the relevant dose constraint), the likelihood and magnitude of potential exposures are negligible and the regulatory body does not consider exemption to be appropriate. This can usually be determined on the basis of previous experience or by means of a preliminary qualitative assessment. Notification makes the regulatory body aware of the discharges and

provides an opportunity for the regulatory body to keep the discharges under review. If notification is to be used, the regulatory body should consider developing clear criteria based, for example, on the radionuclides involved or the maximum activities that are permitted to be acquired in a given time period.

5. THE PROCESS FOR AUTHORIZATION OF DISCHARGES

5.1. Authorization is defined in the GSR Part 3 [3] as the granting by a regulatory body or other governmental body of written permission for a person or organization to operate a facility or conduct specified activities. The control of discharges is one important aspect that should be addressed within the authorization process for a facility or activity and at different stages throughout the lifetime of the facility or activity. Authorization applies to practices for which exemption cannot be granted and notification is not sufficient.

5.2. The regulatory body should establish the authorization process for facilities and activities, including provisions for discharges, using the concept of a graded approach, in accordance with the expected radiological impact on the public and the environment¹⁴.

5.3. An authorization can be granted by means of registration or licensing. Depending on national arrangements, the choice should depend on the level of exposure associated with the facility or activity and the likelihood and possible consequences of an accidental release of radioactive material to the environment.

5.4. Authorization by means of registration should be used for facilities and activities for which:

- (a) Safety can largely be ensured by the design of the facility and the equipment;
- (b) The operating procedures are simple;
- (c) The need for training on safety is minimal;
- (d) Past experience has shown that there are few problems with safety in such types of operation [3].

Registrations are usually expressed in generic terms but may have specific conditions or limits attached. Registration is best suited to those practices for which the risk of exposure is very low and operations do not vary significantly. Examples of practices for which registration may be adequate are those in which small quantities of short lived radionuclides are used for standardized bioassays (e.g. radioimmunoassay). The regulatory body should specify the practices that may be authorized through registration.

¹⁴ DS427 [7] provides guidance for determining whether a simple or complex radiological environmental impact assessment is appropriate for a particular facility or activity and sets out relevant factors in Table 1 of DS427 [7]. The same factors could also be used in applying a graded approach to determining the necessary level of detail in the provisions for discharges to be included in the authorization for a facility or activity.

5.5. Authorization by means of licensing should be applied in all other cases, with the stringency of the associated operational limits and conditions graded in accordance with the expected exposure of the public in normal operation and the likelihood and magnitude of potential exposures, evaluated on the basis of a prospective assessment. The regulatory body should establish the level of stringency of the operational limits and conditions attached to the authorization for discharges, taking into account the likelihood and expected magnitude of exposures, the characteristics of the facility or activity and a number of additional factors such as the characteristics of the source term, the level of expected exposures, the safety characteristics of the activity or facility, such as the types of safety barriers and engineering features present in the design, and the characteristics of the location.

5.6. For simple facilities or activities, such as those with limited amounts of radionuclides with a potential of causing a significant radiological impact on the members of the public and the environment, the authorization process should normally consist of a single stage. The regulatory body could provide generic guidance identifying the necessary elements to be included in the process to determine the discharge limits and, where possible, should provide the methodology for the necessary assessments.

5.7. For complex facilities, such as nuclear installations, there may be multiple stages in the full authorization process, associated with the different stages in the lifetime of the facility, from siting and site evaluation to decommissioning and release from regulatory control. Figure 2, which is adapted from figure 1 in SSG-12 [4], describes schematically the stages in the lifetime of a complex facility, such as a nuclear installation, and the points at which the control of discharges should be considered. The horizontal arrow indicates the evolution of time. The vertical full arrows indicate the stages at which the control of discharges may be part of the preliminary discussions with the regulatory body, up to when the discharge limits are set by the regulatory body, prior to operation. The vertical dashed arrows indicate where a review of the discharge limits can be considered, as a result of operating experience if significant changes have occurred during the operational stage. In some cases, the regulatory body may consider a generic design proposed by a designer of the facility (e.g. the nuclear power plant vendor) to set generic provisional discharge limits prior to a specific site being identified. This would help to make a subsequent site specific authorization process more efficient, especially if the same type of facility is to be built on a number of sites.

5.8. During the siting, design and construction stages of a complex facility, the applicant should provide the regulatory body with information relevant to the optimization of protection

of the public, such as information on possible discharges to atmosphere and to surface water bodies and their radiological impact on the public and the environment, on the generation of waste, and on waste management on the site and its impact on workers. This information should be sufficient to allow the regulatory body to form an opinion about the suitability of the optimization procedure.

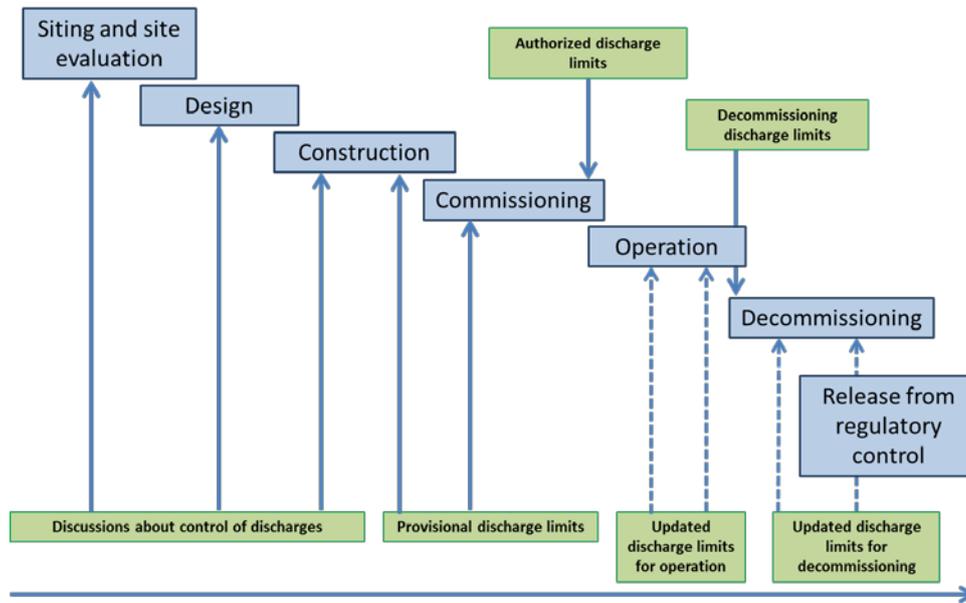


FIG. 2. Example of stages in the lifetime of a facility and the points at which the control of discharges should be considered.

5.9. GSR Part 3 [3] states that, for setting discharge limits, the results of a prospective radiological environmental impact assessment conducted in accordance with the requirements of the regulatory body are required to be considered. Guidance on prospective radiological environmental impact assessment for facilities and activities that should be conducted during or prior to the siting, design and construction stages is presented in DS427 [7].

5.10. The authorization for discharges should be reviewed during the operation stage, for example as part of a periodic safety review of the facility or activity [3]. Significant changes in any condition that could affect public exposure should be taken into account during the review of an existing authorization. Such significant changes could include changes in the characteristics and operation of the facility, changes in the characteristics of the discharges, changes in the parameters that are input to the models used to calculate doses, changes in the habits or location of the population or changes in the environmental dispersion conditions.

5.11. A new, or revised, authorization for discharges may be required when the operational stage ends, in order to take into account the likely changes to the discharges during the decommissioning process. New discharge limits should be established prior to the start of the decommissioning activities. In some situations, operation and decommissioning activities may overlap; due consideration should be given to this eventuality when relevant discharge limits are set.

5.12. The release of a facility from regulatory control after decommissioning depends, in part, upon whether an authorization for discharges is still necessary. For some practices (e.g. uranium mining or processing), some form of control of public exposures may be necessary after decommissioning, for exposure to residual discharges to the environment that may still occur. For such situations, the regulatory body should specify the control measures necessary after decommissioning to minimize public exposure and, when relevant and on a case by case basis, the necessary environmental monitoring programme.

DEVELOPMENT OF AN AUTHORIZATION FOR DISCHARGES

5.13. The regulatory body should establish the process to be followed by an applicant seeking an authorization for discharges once the need for an authorization for discharges has been established. The steps of the authorization process may be as follows:

- (a) The regulatory body should specify the relevant dose constraint for the facility or activity under consideration (see paras 5.15 to 5.19 and Annex I).
- (b) The applicant should characterize the discharges and the main exposure pathways identified, in order to assess adequately the exposure of the representative person.
- (c) The applicant should present the measures to be used for the optimization of protection and safety of the public, having given consideration to measures for keeping the exposures due to discharges as low as reasonably achievable, and taken into account all relevant factors.
- (d) The applicant should assess the doses to the representative person. This may involve a number of iterations, starting with a simple cautious generic assessment and, if necessary, a more detailed, site specific study.
- (e) The applicant should submit the results of the assessment to the regulatory body. The regulatory body should evaluate whether the models and assumptions used by the applicant are appropriate, should compare the results of the assessment with dose limits and dose constraints and should evaluate whether the assessed doses are in accordance with the need to provide optimized protection for the public

- (f) The regulatory body should set the discharge limits and should establish conditions by which compliance during operation is to be demonstrated, including by means of source monitoring and environmental monitoring systems and programmes.
- (g) The regulatory body should issue an authorization for discharges upon its satisfaction that the models and assumptions are valid and the doses will not be higher than the optimized levels.

Figure 3 illustrates the process for setting discharge limits in accordance with the steps described above. The various elements in the process are described in the following sections.

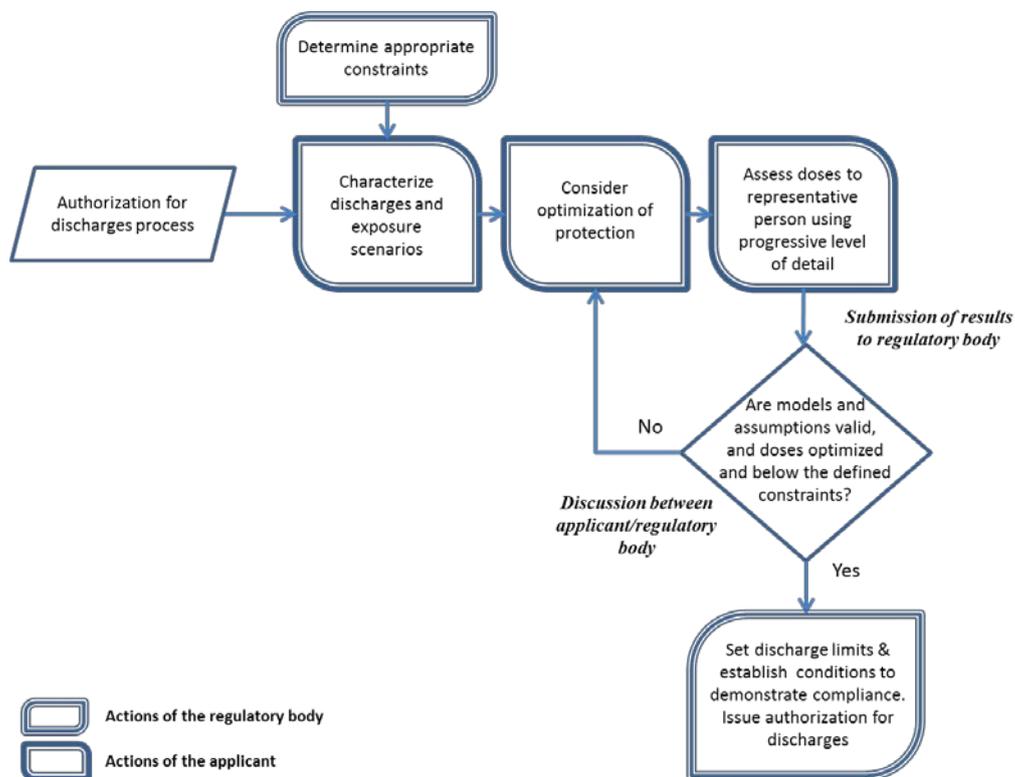


FIG. 3. Steps in setting discharge limits, indicating those responsible. [can we edit a bit – determine

5.14. The process illustrated in Fig. 3 identifies actions of the regulatory body and actions of the applicant. In setting the discharge limits there should be regular engagement and discussion between the applicant and the regulatory body with regard to the validity of the assumptions made to estimate doses, the optimization process and the implications that the discharge limits and the operational limits and conditions under discussion may have for the

operation of the facility or conduct of the activity. The implications of the storage of any liquid and gaseous radioactive waste that is not discharged to the environment and the associated doses to workers should also be considered. This process should be conducted in an iterative manner in order to reach an acceptable optimum solution from the point of view of safety and radiation protection.

ESTABLISHING A DOSE CONSTRAINT FOR THE CONTROL OF DISCHARGES

5.15. The government or regulatory body is responsible for establishing or approving the source related dose constraints to be used in the optimization of the protection of the public during normal operation. The dose constraint for each particular source is intended, among other things, to ensure that the sum of doses from planned operations of that source and of all the authorized sources that may contribute to the exposure of the public remains within the dose limit. In specifying the dose constraint, the contribution to exposure due to local sources and regional sources may be considered.

5.16. The dose constraint, set for a single source, should be expressed in terms of annual effective dose; it should be below the limit set for the effective dose to the public in planned exposure situations from all regulated sources (i.e. 1 mSv in a year, as required in GSR Part 3 [3]), and higher than a dose of the order of 10 μ Sv in a year. Therefore, in practical terms, dose constraints should be selected within the range of 0.1 to <1 mSv in a year¹⁵ [7].

5.17. Dose constraints should be used for planning measures for protection and safety as part of a prospective assessment and should not be used as alternative dose limits to be applied during facility operation. More specifically, exceeding a dose constraint should not represent a regulatory infraction, as would be the case if the dose limit were to be exceeded.

5.18. In setting a dose constraint, the government or the regulatory body should take the following into account:

- (a) The characteristics of the location that are of relevance for the level of public exposure, for example exposure pathways, habit data and time occupation factors.
- (b) The possible contribution to the dose from other authorized facilities and activities or foreseeable future facilities and activities.

¹⁵ The regulatory body may determine what additional restrictions, if considered necessary, are required to ensure that the dose limits specified in GRS Part 3 for the public in planned exposure situations are not exceeded owing to possible combinations of doses from exposures due to different authorized practices [3].

5.19. Although dose constraints should be set at a value that depends on the specific facility or activity and the expected exposure conditions at its location, national authorities may choose to develop generic dose constraints, for facilities or activities of a similar design or characteristics (e.g nuclear installations, uranium mining and processing, industrial and medical applications). The specification and use of generic and specific dose constraints in the process of optimization of the protection of the public is described further in Annex I.

CHARACTERIZATION OF DISCHARGES AND EXPOSURE SCENARIOS

5.20. A pre-operational analysis should be carried out to identify the inventories of radionuclides that would result in discharges during operation of a facility or conduct of the activity, the possible discharge routes, the amounts that would be discharged to the environment and the radiation exposure pathways, and other relevant data that could be used to estimate doses to members of the public. This could be based on specific analysis for the practice under consideration or based on the experience in similar practices.

5.21. The need for a detailed characterization of the discharges should depend on the expected magnitude of the dose to the members of the public, in accordance with a graded approach. For small facilities or activities using unsealed radioactive material, such as nuclear medicine departments in hospitals, and research laboratories, consideration should be given to whether the discharges can be assessed on the basis of the estimated throughput, with allowance made for radioactive decay. For nuclear fuel cycle facilities, estimates of discharges should be made from consideration of the design, proposed operating characteristics and efficiency of the techniques used to reduce the discharges. Information from similar facilities or activities already in operation elsewhere could also be used [21]. [check ref – UNSCEAR 2008 is correct?]

5.22. The relative importance of different exposure pathways is dependent upon the nature and route of the discharges and the physical and chemical characteristics of the radionuclides. The characterization of the radiation exposure pathways should take into account whether discharges are to the air or water, and, in the case of liquid discharges, whether the discharge is to a marine, estuarine or freshwater environment. In the case of discharges to the atmosphere, consideration should be given to the meteorological data for the site and its surroundings and the possible deposition of radioactive substances on land and subsequent transfer to crops and animals. In the case of discharges to water, consideration should be given to the uses of the water, such as for consumption, fisheries and production of aquatic

food, irrigation and recreation. Some facilities, such as hospitals and small research laboratories, may discharge radionuclides to the sewerage systems, which could lead to exposures of individuals through their occupation (e.g. sewage treatment plant workers¹⁶) or through the use of sewage sludge for land fill or agricultural purposes. Guidance on the selection of exposure pathways, the use of meteorological and hydrological data and environmental transfer and the estimation of doses can be found in DS427 [7]

5.23. Preoperational studies should also be carried out to determine the existing levels of background radiation in the area surrounding the facility prior to its operation and should include the determination of the external radiation levels as well as the concentrations of radionuclides in the environment (e.g. water, soil, plants, crops, food). These studies should be used to establish a baseline above which the actual impact of the discharges can be determined. This baseline can vary from site to site because of variations in natural background radiation and possible residual contamination from past practices, accidents or global fallout after nuclear weapon tests. The establishment of a baseline is particularly important for practices that discharge naturally occurring radionuclides (see Section 6). Detailed guidance on undertaking preoperational surveys is given in RS-G-1.8 [9] and Ref. [22].

5.24. If a discharge could cause significant public exposure outside the territory or other area under the jurisdiction or control of the State in which the discharge takes place, the operating organization should make an assessment of the radiological impacts of the discharges on the public and, as necessary, on the environment in these areas. This is particularly important when the individuals likely to receive the highest doses may live in a neighbouring State, for example, in the case where a facility is to be constructed close to a national border or on an international waterway.

CONSIDERATION OF OPTIMIZATION OF PROTECTION AND SAFETY

5.25. Optimization of protection and safety is the key process in establishing an authorization for discharges and it involves a number of different aspects. In relation to a discharging

¹⁶ Such workers are subject to the dose limits for members of the public; see para 3.78 of GSR Part 3 [3].

facility that may cause public exposure, optimization should be part of the design and planning process and should also be kept under review throughout the lifetime of a facility. Optimization in relation to discharges forms part of the optimization of protection and safety for the practice as a whole.

5.26. Optimization of protection with respect to the radioactive discharges is not simply a matter of considering the balance between the radiation risks associated with the discharges during normal operation and the costs of making any reductions. The impact of decisions on waste management on exposures of the worker and the safety of the facility as a whole should also be considered. For example, a reduction in discharges may lead to an increase in radioactive waste stored on the site, with related increases in occupational exposures, so that this may not be the optimum solution. Guidance on the optimization of the design of a facility or an activity with respect to management of radioactive waste can be found in GSG-3 [23].

5.27. Optimization should involve examining the available options for reducing discharges and all aspects of the impact of these options. Much can be achieved at the early stages of siting and design, when account can be taken of good techniques and practices applied in other facilities and activities. In the case of liquid and gaseous radioactive waste that might be generated during operation, consideration should be given to keeping the waste to a minimum and to the subsequent treatment of the radioactive effluents.

5.28. The main types of treatment of radioactive effluents are either storage, so that, for example, short lived radionuclides present in liquid and gaseous forms can decay before they are released to the environment, or abatement techniques that remove radionuclides from the effluent stream (e.g. ion exchange resins, HEPA filters). Within these two broad categories, there may be a number of different options available; these options should be identified and their advantages and disadvantages should be examined.

5.29. Optimization of the protection and safety should be conducted considering the dose constraints and the range of available protection options. An iterative analysis of the impact on the doses to the public and to the workers for each selected protection option should be performed.

5.30. There are generally a number of trade-offs and other factors between various options that should be considered in the optimization process. These include the following:

- (c) A trade-off between doses from discharges and future doses associated with the disposal of solid waste, if a decision was made to solidify the residues;

- (d) A trade-off between public exposure and occupational exposure (i.e. the reduction in public exposure at the expense of an increase in occupational exposure due to an improved effluent treatment system);
- (e) Choices between options whose characteristics are known with different degrees of certainty;
- (f) Non-radiological impacts, conventional health and safety
- (g) The increased risk of accidental releases (e.g. if a large storage tank leaks) .

5.31. Irrespective of the approach used in determining the optimum option, it should be recognized that judgements are necessary regarding the relative significance of the factors involved. Making those judgements should involve dialogue between the regulatory body and the operating organization. The discussions on optimization could also involve different authorities, such as authorities responsible for nuclear safety, protection of workers, protection of the public and environmental protection.

5.32. When the projected doses to the members of the public are of the order of 10 μ Sv per year or below, a process for optimization should not normally be required, on the basis that the efforts for further dose reduction would generally not fulfil the requirement for optimization.

Optimization of protection and regulatory control of specific radionuclides

5.33. While the requirements for optimization of protection and regulatory control must be applied to all type of facilities and activities and radionuclides, in carrying out the optimization of protection, certain effluents containing radionuclides used in some practices have special characteristics that require particular consideration. Among these characteristics are the technical difficulties in managing radioactive waste from applications of radioisotopes in medicine or from the operation of certain facilities or the conduct of certain activities. Examples are the use of unsealed sources in nuclear medicine, which are administered to patients as part of medical treatment, or the management of large volumes of the gaseous or liquid effluents containing very low levels of activity concentration of certain radionuclides resulting, for example, from neutron activation in the coolant system of nuclear power plants.

5.34. For such practices, the discharge of some specific radionuclides may require special consideration by the operating organization and the regulatory body at the time of specifying and agreeing the optimal solution in terms of the protection and safety. This consideration may also result in the need for an adapted approach for the regulatory control of these

discharges. Examples of such radionuclides are tritium and carbon-14 discharged from some nuclear installations and iodine-131 used in hospitals for nuclear medicine therapy.

5.35. For these particular practices and radionuclides, the operating organization should specify, in discussion with the regulatory body, the optimum option for discharges, taking into account the following:

- (a) Technical characteristics relating to the control of discharges of these radionuclides, such as the availability of abatement techniques on a scale consistent with the needs for the particular practice (in particular for large volumes of liquid or gaseous effluents with low concentrations of radionuclides);
- (b) Economic characteristics, such as the costs of the waste abatement techniques, which might be excessive and unjustified in the framework of the general optimization of protection and safety for the type of practice;
- (c) Societal considerations, such as public acceptance of the type of practice under consideration, as well as individual and societal benefits derived from the type of facility or activity;
- (d) Environmental and efficiency considerations, such as the effects of any releases of hazardous chemical substances or high energy consumption entailed by the waste abatement techniques;
- (e) Safety considerations, such as those relating to the safe storage of large amount of radioactive solid, liquid or gaseous material for long times, as well as the risk of accidental releases;
- (f) Issues relating to the management of radioactive waste, such as issues relating to the transport and storage of large quantities of low level waste¹⁷;
- (g) Radiation protection considerations, such as individual doses and collective doses received by workers in connection with the abatement process and with the storage of waste.

5.36. The regulatory body and the operating organization should take into account that, for the above mentioned specific practices and radionuclides, the optimal management option from a radiation protection perspective might not result in the application of particular costly waste abatement techniques, but in the application of more stringent measures for the

¹⁷ Low level waste is waste that is above clearance levels, but with limited amounts of long lived radionuclides (see Classification of Radioactive Waste, IAEA Safety Standards Series No. GSG-1 [24]).

verification of compliance by the operating organization and the regulatory body, as relevant. The optimal management option and the justification of the selection of this option should be presented by the operating organization and endorsed, if acceptable, by the regulatory body. Examples of more stringent measures for verification of compliance for complex facilities, including nuclear installations, are: a radionuclide specific source monitoring and environmental monitoring programme; more detailed assessment of the dose to the representative person, including the identification of relevant exposure pathways; and more frequent reporting of discharges to the regulatory body.

Decision aiding techniques

5.37. Depending upon the circumstances, the process of optimization of the protection of the public can include the use of a variety of quantitative and qualitative techniques. Formal decision aiding techniques should be used as appropriate in the optimization process. The advantage of formal decision aiding techniques is that they allow each of the elements involved in making a decision to be explicitly identified. If the doses to the representative person are assessed to be very low (e.g. of the order of 10 μ Sv in a year or less), a formal analysis of the optimization of protection will generally not be necessary.

5.38. Various analytical techniques have been proposed to assist in determining the optimized level of protection, which may be applied for discharges [25]. Decision aiding techniques include cost–benefit analysis and multi-criteria methods. The main limitation of cost–benefit analysis is that it requires explicit valuation of all factors in monetary terms. This tends to restrict the range of factors that can be included in the optimization process. Multi-criteria methods do not necessarily require such explicit valuation and are potentially more flexible decision aiding techniques because they allow additional factors to be considered. For example, equity in time and space, risk perception of the public and the potential for an accidental release are additional factors that can be taken into account by means of multi-criteria methods. The distributions over time of investments and operating costs can also be considered.

Best available techniques

5.39. In optimizing the protection of the public, the measures used in the management of radioactive waste and effluents and the way they are applied should be considered and compared with other possible options. Concepts such as ‘best available techniques’ are applied in some States [26] and under certain international frameworks [27, 28] and in other industries for controlling pollutants generally. The use of best available techniques

corresponds to optimization if the techniques are verified and their use is not simply a matter of considering what techniques are or could be available for reducing discharges, but rather considering the situation as a whole to determine the optimum level of protection, including the availability of the options and the costs involved. Application of the concept of best available techniques to particular processes, facilities or methods of operation to reduce discharges of radionuclides to the environment is described in more detail in Annex I in the framework of optimization of protection.

Use of collective dose

5.40. The estimation of collective doses to members of the public resulting from alternative options for managing discharges and their comparison is another approach that could be included in the optimization process.

5.41. The collective dose is the total radiation dose from a source incurred by a given group of population [3] and it can be obtained by multiplying the average dose to the exposed group by the number of individuals in the group [25, 29]. When estimating the collective dose to the public, care should be taken to avoid inappropriate aggregation of, for example, very low individual doses over extended time periods and wide geographical regions, i.e. truncating conditions should be set [25]. Collective dose should be used only in the comparison of options, and any truncation applied to the calculations has to be consistent so that the comparisons are meaningful.

5.42. Use has been made of collective dose in different ways to assist in the selection of an optimum level of protection of the public, for instance to assign a monetary cost to the radiation detriment and to compare this with the cost of each option to reduce discharges. This Safety Guide does not provide detailed guidance on the use of collective dose; however, with adequate consideration and care, the use of collective dose could be a practical means to apply optimization, by comparing the protection outcome of different technologies. Collective dose must not be used to attribute specific risk of health effects [UNSCEAR 2012 Report]. ICRP Publication 101 [25] describes optimization and the use of collective dose in more detail.

ASSESSMENT OF THE DOSE TO THE REPRESENTATIVE PERSON

5.43. The establishment of an authorization for discharges should take into account the results of an assessment of the radiological environmental impacts commensurate with the radiation risk associated with the facility or activity [3, 7]. To set the discharge limits, prospective

estimations of the dose to members of the public should be used to determine acceptable optimized discharge levels that meet the established radiological criteria.

5.44. The estimation of the effective dose that may be incurred by members of the public depends upon a number of factors, such as the characteristics of the source term, 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. For the purpose of setting discharge limits, the dose to an individual receiving a dose that is representative of the doses to the more highly exposed individuals in the population (i.e. the representative person) should be assessed. The dose to the representative person “is the equivalent of, and replaces, the mean dose in the ‘critical’ group” [25].

5.45. Before starting the estimation of doses to the representative person, a judgement should be made by the applicant regarding the scope and level of detail and the resources that should be allocated to the assessment. These matters should be discussed with and should be subject to the agreement of the regulatory body.

5.46. The level of detail of the assessment model should depend upon the type of facility under consideration, the nature of the discharges and the availability of information and should be consistent with a graded approach. In order to make effective use of assessment resources, a structured iterative approach for assessing doses to the representative person may be useful. Such an approach should start with a simple assessment based on very cautious (conservative) assumptions and should be refined with each iteration, using progressively more complex models with more realistic assumptions and site specific data, as necessary.

5.47. Consistent with a graded approach, the use of generic assessments should be limited to assessing the impacts from small and simple facilities or activities with standardized practices that result in foreseeable low to very low discharges. DS427 [7] provides guidance for conducting assessments at different levels of detail and realism. Depending on its characteristics, the facility or activity can have discontinuous discharges and can lead to exposure of members of the public within its premises (e.g. hospitals using iodine-131 for diagnosis and therapy) or to exposure of workers who are not normally subject to monitoring for occupational exposure (e.g. such as workers in external plants treating the effluents from the facility or activity); such situations should be considered carefully in the assessments.

5.48. To estimate doses to the representative person, a generic approach may also be used at the early stages in the lifetime of a complex nuclear installation (see Fig. 2), such as during initial discussions about the control of discharges or to set provisional discharge limits. This should be followed by a more site specific, realistic assessment once more information becomes available during the authorization process. DS427 [7] provides guidance on the level of detail and the type of information needed to conduct a prospective radiological environmental impact assessment for different facilities and activities during the process of authorization, which also applies to the assessments used to establish discharge limits.

5.49. When estimated doses to the representative person are above the dose constraint, the reduction of projected discharges or a change in their characteristics (for example, a change in the location of the point of discharge) should be considered. Otherwise, a more detailed assessment (using site specific data or more realistic models) should be conducted. In any case, if a generic cautious assessment is used then it should be ensured that this does not unduly affect the optimization process. Adopting cautious assumptions in the calculations that are likely to significantly over-estimate the doses estimated could lead to decisions that do not meet the radiation protection principle of optimization.

5.50. The habits (e.g. consumption of foodstuffs, indoor or outdoor occupation factors, consumption of locally produced foods) adopted to characterize the representative person should be typical habits or characteristics of a small number of individuals representative of those more highly exposed. The highest percentiles in the distribution of the habit data of certain exposure pathways (e.g. the 95th percentile), such as consumption of milk and crops, should be used to characterize the representative person. However not all extreme habits should be used to represent a single member of the population, so as to avoid over-estimation. Extreme or unusual habits should not dictate the characteristics of the representative person considered [25].

5.51. In assessing doses to the representative person from discharges to the environment, the following three main exposure pathways should be considered:

- (a) External exposure from radionuclides present in the environmental media;
- (b) Internal exposure from the inhalation of radionuclides present in air;
- (c) Internal exposure from the ingestion of radionuclides incorporated in water and foods.

External exposure may be caused by radioactive substances suspended in the air or deposited on the ground or other surfaces. More details on the exposure pathways relevant for assessment of doses to the representative person are provided in Refs [7, 15].

5.52. In some facilities or activities, radiation sources can contribute to the external exposure of members of the public located in the close vicinity, through direct gamma irradiation and, in some cases, sky scattered gamma ray radiation (sky shine). Examples are sources of radiation stored at the facility (e.g. spent fuel or radioactive waste), sources used in the facility or activity (e.g. industrial irradiators) and components of the facility (e.g. nuclear reactors or coolant systems or steam systems). When direct irradiation influences the exposure conditions of the representative person, the resulting doses should be estimated and taken into account when setting discharge limits, so that the established dose constraint is not exceeded.

5.53. Given that the initial authorization for discharges from a facility or activity is based on a prospective assessment, mathematical environmental models should be used to assess the activity concentrations in the air or water. Subsequently, environmental transfer models and parameters should be used to assess the activity concentrations in other environmental media relevant for the estimation of doses (e.g. sediments or food products). Dispersion and transfer parameters are given in Ref. [15]. The possible accumulation or build up of long lived radionuclides and the ingrowth of radioactive progeny in environmental media should be taken into account.

5.54. Models for the assessment of dispersion and transfer in the environment should be adequate for the situation in which they are being applied, to ensure that the assessment methodologies are suitable for demonstrating that there is a high likelihood that all compliance requirements can be met under all reasonably foreseeable conditions. Models should be verified. Where possible, the selected models should be validated through comparison of the results with data for similar exposure scenarios or, at least, by means of benchmarking procedures against other adequate models. Different methods, including different calculation tools and input data, can be used to carry out an assessment [15]. The regulatory body should decide in discussion with the applicant and other interested parties, which methodology is best suited to carrying out a particular assessment and should agree that the methodology adopted is adequate for its proposed purpose. DS427 [7] provides more information on the assessment methodologies and the characteristics of models and data to be used in the assessment of discharges during normal operation.

5.55. Different age groups should be considered when determining the exposure of representative person. It is generally sufficient to consider exposures of three age groups (1 year old infants, 10 year old children, and adults). Exposure of the embryo or fetus and breast fed infants may also need to be considered in some limited circumstances [25], for example when, due to the radionuclides to be discharged, the exposure of the embryo or fetus and breast fed infants may be more significant (e.g. discharges of radioiodine).

5.56. When identifying the representative person it should be ensured that not only the groups of individuals closest to the facility or activity are considered. Population groups at more distant locations which, in view of their habits, could be more exposed due to their specific living habits. For example, this could be a group of individuals living in a town at some distance from the plant, but eating fish from a catchment area close to the discharge point.

5.57. The location and lifestyle habits of the representative person should be specified with regard to present and, as reasonably foreseeable, future environmental conditions, land use, spatial distribution of population, food production, distribution and consumption and other relevant factors, with account taken of the projected lifetime of the facility or activity.

5.58. When determining the location and lifestyle habits of the representative person for remote sites with only a small local population or no local population, consideration should be given to developing a theoretical representative person based on a reasonable exposure scenario that captures land use practices, such as fishing, hunting or other seasonal or periodic land use practices that may be associated with a nearby community.

AUTHORIZATION FOR DISCHARGES AND OPERATIONAL LIMITS AND CONDITIONS

5.59. The authorization for discharges should take the form of written permission from the regulatory body. The regulatory body may grant an application for an authorization for discharges on a justified basis or may impose additional conditions or operational limitations that it deems appropriate for the purposes of protection and safety.

5.60. The regulatory body should record formally the basis for its decision on an authorization for discharges, or on the amendment, renewal, suspension or revocation of the authorization for discharges, and should inform the applicant, in a timely manner, of its decision, including the reasons and justification.

5.61. In granting an authorization for discharges, the regulatory body should establish or approve authorized limits for discharges. These should take into account the results of optimization of protection and safety and should be set in accordance with a graded approach.

5.62. Large complex facilities such as nuclear installations are subject to an extensive authorization process, which should include provisions for discharges and establish in detail the relevant operational limits and conditions. Operational limits and conditions associated with the authorization for discharges for such facilities should be expressed in terms that the operating organization can reasonably be expected to control, for example in terms of measured discharges (total activity or activity concentrations and gaseous or liquid volume discharged) rather than doses to the public, which can only be estimated. The operational limits and conditions associated with the authorization for discharges for simpler facilities, such as hospitals with small nuclear medicine departments, industrial applications or small laboratories, should be less onerous. The use of discharge limits expressed in dose versus discharge limits expressed in activity amounts in the authorization for discharges is described further in Annex I.

5.63. Discharge limits should be attached or incorporated into the authorization granted to the facility or activity, so they become regulatory limits with which the operating organization or licensee should comply.

5.64. The period of validity of the discharge limits should be specified in the authorization for discharges or in another related regulatory document, with a provision for their review whenever deemed appropriate by the regulatory body, but at least once every ten years. The period of validity of discharge limits for complex facilities, such as nuclear power plants, nuclear fuel reprocessing facilities and radioisotope production facilities, should be the same as the period of validity of the authorization for the facility, subject to a periodic review. .

5.65. A review of the authorization for discharges should be conducted whenever modification of the facility or of the operational limits and conditions attached to the authorization is expected to affect significantly the characteristics of the discharges. Nuclear facilities and other complex installations have periodic safety reviews after intervals of ten years that should include the review of the authorization for discharges. More simple facilities, such as facilities or activities using limited amounts of radioisotopes, should be reviewed periodically but at longer intervals. The discharge limits for a new practice for which experience is limited should be reviewed by the regulatory body after an adequate time

when sufficient operational experience has been gathered, for instance within the first three years.

5.66. The operational limits and conditions in an authorization for discharges should include, as appropriate, some or all of the following:

- (a) Restrictions relating to different operational states of the facility (e.g. separate authorized limits for maintenance and for normal operation), different seasonal conditions and different environmental dispersion conditions. For example, a restriction may be specified for facilities discharging to a river when the water level is low because of very dry weather in a particular season, or when the river is prone to flood. Similarly, in the case of discharges to a tidal marine environment, the regulatory body may specify the period of the tidal cycle at which the discharge should take place to ensure maximum dispersion;
- (b) Limits on the activities or activity concentrations of radionuclides or groups of radionuclides that can be discharged in a given time period (e.g. monthly, quarterly or annually);
- (c) Requirements for source monitoring and environmental monitoring programmes and systems and the frequency for reporting of results to the regulatory body (the regulatory body should specify the form and the required content of the reports);
- (d) Requirements for the maintenance of the appropriate records;
- (e) Requirements for the reporting to the regulatory body of proposed modifications and of any revisions to the radiological environmental impact assessment;
- (f) Actions to be taken in the event of exceeding of authorized discharge limits or breaching of operational limits and conditions;
- (g) Period of validity of the authorization for discharges for the facility or activity and interval for the periodic review.

5.67. The discharge limits should include a margin for flexibility to provide for operational variability and for anticipated operational occurrences. How much operational flexibility should be permitted is a matter of judgement on the part of the regulatory body, but as a minimum it should allow for discharges that are anticipated for normal operation, such as an increase in the throughput of patients in a nuclear medicine department or an increase in atmospheric discharges from a nuclear power plant during maintenance. Previous experience from similar facilities can provide useful information on the minimum allowance for

flexibility that should be permitted [30]. The need for operational flexibility should be considered as part of the optimization process in setting the discharge limits.

5.68. Discharge limits should be specified for different radionuclides, or groups of radionuclides depending on:

- (a) The feasibility of measurement of the individual radionuclides;
- (b) The significance of the radionuclides in terms of dose to the representative person;
- (c) The relevance of the measurement of the individual radionuclides as an indicator of the performance of the facility or activity.

5.69. In addition to the discharge limits for groups of radionuclides, discharge limits could be specified for particular radionuclides. These radionuclides should be identified on the basis of their special significance, for instance their radiological importance or other aspects, such as the involvement of large volumes of liquid or gaseous waste with very low levels of activity concentration. Examples of such radionuclides are caesium-137, cobalt-60, carbon-14 and tritium (carbon-14 and tritium are addressed in paras 5.33 to 5.36). In some cases the regulatory body may also impose limits on specific radionuclides that have low radiological significance, but which provide early indications of important changes in the operational or safety status of the facility (e.g. tritium and noble gases from purges in the coolant systems or steam systems in nuclear reactors).

5.70. Discharge limits for groups of radionuclides rather than for individual radionuclides may be appropriate when the radionuclides share relevant characteristics so that they can be measured with gross counting techniques. The use of scaling factors for relating one measured radionuclide to others should be applied for radionuclides that cannot be promptly analysed as part of routine measurements at a nuclear installation (for example, nickel-63, iron-55 and strontium-90). Scaling factors should be derived from a sufficient number of detailed measurements to determine the characteristic radionuclide composition in the effluents, using adequate methods and taking into account detection limits. The scaling factors should be reviewed periodically.

5.71. The grouping of radionuclides should take into account not only the different ways of sampling and quantifying the discharges, but also dosimetric considerations. For example, airborne discharges from nuclear installations are often grouped as noble gases, halogens or iodine radioisotopes, and particulates. This grouping reflects that noble gases result in external exposure of the whole body; iodine radioisotopes result in thyroid doses; and

particulates usually present a potential hazard from inhalation or ingestion to all of the organs and tissues of the body.

5.72. The grouping may also be extended to include gross alpha and gross beta activities. When limits are specified for groups of radionuclides measured by gross alpha or gross beta counting, the discharge limit for the group should be set on the basis of the characteristics of the radionuclide that gives the highest dose per unit activity discharged. In the case of uranium discharges, a limit expressed as a mass in kg per year, with consideration of the contribution of each uranium isotope, may be more appropriate than a limit on gross alpha activity.

5.73. The regulatory body should include in the authorization for discharges, or in other regulatory documents, conditions and anomalies to be reported, such as:

- (a) Any levels exceeding the operational limits and conditions relating to public exposure, including authorized limits on discharges, in accordance with reporting criteria established by the regulatory body;
- (b) Any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the authorized practice, in accordance with reporting criteria established by the regulatory body.

This is further described in paras 5.88 to 5.91.

5.74. The operating organization should make available, on request, results from source monitoring. This request may be incorporated within the operational limits and conditions of the authorization or specified in other regulatory documents. Annex I provides further information on the possible forms of an authorization for discharges.

DEMONSTRATION OF COMPLIANCE

5.75. In order to demonstrate that discharges are in compliance with the limits and in order to check the assumptions used to evaluate doses to the representative person, monitoring programmes should be established [9]. Two general types of monitoring are appropriate in the context of the control of discharges and the related public exposure:

- (a) Monitoring of the source, which involves measuring activity concentrations or dose rates at the discharge point or within the activity and facility (i.e. at the stack or the discharging pipelines or at the reservoirs prior to discharge);

(b) Monitoring of the environment, which involves the measurement of radionuclide concentrations in environmental media (including foodstuffs and drinking water) and doses or dose rates due to sources in the environment.

5.76. The requirements for source monitoring and environmental monitoring should be specified in the authorization for discharges by the regulatory body. The necessity for and frequency of monitoring should be determined by the assessed level of risk of radiological impact.

5.77. Monitoring programmes should be developed and conducted in line with a graded approach. For example, routine environmental monitoring is unlikely to be necessary in the case of discharges from a hospital with a nuclear medicine department or small research laboratories using short lived radionuclides [9]. Rather, a single monitoring campaign, close to the facility prior to and at the beginning of operations may be considered by the regulatory body as sufficient to verify compliance. However, even for such simpler facilities, changes in operational procedures can lead to increased discharges and as such may necessitate a review of the need for monitoring.

5.78. Source monitoring and environmental monitoring should normally be undertaken for facilities in the nuclear fuel cycle [9].

5.79. For complex facilities, such as nuclear power plants or reprocessing facilities, monitoring programmes should also provide an additional means of checking the operating conditions of the facility and to provide a warning of unusual or unforeseen conditions resulting in the possibility of unexpected releases.

Monitoring by the operating organization

5.80. The operating organization should establish and use the monitoring programme to verify and demonstrate compliance with the authorization and to enable adequate assessment of public exposures due to sources for which they are responsible. The monitoring programmes developed by operating organizations should be subject to approval by the regulatory body. RS-G-1.8 [9] provides comprehensive guidance on source monitoring and environmental monitoring applicable to control of discharges. Additional technical information on programmes and systems for source monitoring and environmental monitoring is available in Ref. [22].

5.81. Some secondary objectives, which should usually be fulfilled by a monitoring programme, are to provide information for the public; to maintain a continuing record of the impacts of a facility or an activity on radionuclide levels in the environment; and to check the predictions of environmental models in order to reduce uncertainties in the dose assessment [9]. In accordance with these objectives, the monitoring programme should also include the collection of relevant supporting information, such as meteorological and hydrological data when this is considered necessary, in accordance with the radiation risk presented by the level of discharges.

5.82. The operating organization should establish an appropriate quality assurance programme covering control of discharges and the monitoring programme. The programme should set out the corrective actions that should be taken in the event of deficiencies in control and monitoring being identified. It should cover both sample collection and measurement.

5.83. Measures to satisfy the following specific conditions should be incorporated into the quality assurance programmes, as relevant:

- (a) Requirements relating to source monitoring and environmental monitoring and to the collection of representative samples, including the identification of the environmental media and the associated sampling frequency;
- (b) Requirements relating to the accreditation or qualification of analytical laboratories¹⁸;
- (c) Procedures for the calibration and performance testing of measurement equipment;
- (d) A programme for intercomparison of measurements;
- (e) A record keeping system;
- (f) A reporting procedure that is in compliance with requirements of the regulatory body.

Independent monitoring by the regulatory body

5.84. The regulatory body should make provision for independent monitoring. The characteristics of independent monitoring and the resources devoted to independent monitoring should be based on a graded approach and should incorporate best practices and scientifically sound analytical methods. Such monitoring may be undertaken by the regulatory

¹⁸ If accreditation is used as a means to demonstrate qualification, the related requisites should be made available to the laboratory concerned.

body or by another organization on behalf of the regulatory body that is independent of the operating organization.

5.85. The purpose of such independent monitoring may be one or more of the following:

- (a) To verify the quality of the results provided by the operating organization;
- (b) To verify the assessment of doses to the representative person;
- (c) To determine the consequences of any unforeseen release of radioactive material;
- (d) To undertake research into exposure pathways, including the contributions to dose of other sources of exposure;
- (e) To provide public reassurance.

Retrospective assessment

5.86. An additional means of demonstrating compliance is to carry out a retrospective assessment of the radiological impact of the discharges. This should include the assessment of doses to the representative person from measurements taken as part of the source monitoring or environmental monitoring programmes and should consider the relevance of the exposure pathways and related information that were assumed in the prospective assessment of the possible discharges in setting the limits originally.

5.87. The results of retrospective assessments using environmental monitoring data should only be compared with the doses used to derive the discharge limits with careful consideration. Because of the cautious nature of models for environmental dispersion and transfer used in prospective dose assessments, the doses to the representative person determined retrospectively using environmental monitoring data will, in general, be lower than those calculated using data from source monitoring. Measurements in the environment may also be below limits of detection, and may include contributions from other installations, past accidental releases or fallout from past nuclear weapon testing, or may not be representative because of the characteristics in the frequency and spatial coverage of the environmental sampling techniques (which result in data reduced in time and space).

Records and reporting

5.88. Records of the results of source monitoring and environmental monitoring and verification of compliance, including retrospective assessment of the radiological impact of the discharges, should be retained by the operating organization [9]. The regulatory body should establish the content and the frequency of the reporting of such results.

5.89. Reports from the discharge monitoring programmes should include the main operational and discharge data in the period covered by the report and a conclusion on trends observed by comparison with previous results. Such reports should indicate whether the discharges are within the authorized limits established by the regulatory body or as approved for particular operating conditions. Results of audits and inspections, as well as documents relating to the quality assurance or quality control of laboratory analytical procedures and data, should be included as relevant in the reports.

5.90. The operating organization should make provisions to report promptly to the regulatory body any releases exceeding specified reporting levels or authorized discharge limits, in accordance with criteria specified in the authorization for discharges, or in other applicable documents issued by the regulatory body.

5.91. The operating organization should also report any significant abnormal increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the facility or activity.

INSPECTION AND ENFORCEMENT

5.92. The regulatory body should verify compliance with the regulatory requirements and the operational limits and conditions of the authorization for discharges. This should involve, as appropriate, auditing of the operating organization's records (including those setting out the results of discharge monitoring and environmental monitoring), review of the periodic reports on the results of the radiological environmental impact assessment, inspections and review of the results of the independent monitoring programmes.

5.93. The regulatory body should establish a process for identifying and managing any identified non-compliance with the regulatory requirements on discharges. When a regulatory requirement, including a condition of the authorization, has not been met, the operating organization should, as appropriate:

- (a) Investigate the breach and its causes, circumstances and consequences;
- (b) Take appropriate action to remedy the circumstances that led to the breach and to prevent a recurrence of similar breaches;
- (c) Promptly communicate to the regulatory body the causes of the breach and the corrective or preventive actions taken or to be taken;

(d) Take whatever other actions are required by the regulatory body.

5.94. The actions to be taken by the regulatory body in response to non-compliance should be graded in accordance with the seriousness of the failure. Depending on the national legal and regulatory system, such actions may range from a simple warning, legal procedures, including prosecution, and imposition of fines, through to suspension or withdrawal of the authorization.

5.95. Discharge limits are set taking into account the relevant dose constraints and the process of optimization, so any breach of discharge limits will generally not result in a breach of the dose limit. However any breach of discharge limits should be reported to the regulatory body and should result in an investigation and, if necessary, follow-up actions to improve the situation.

Amendment, renewal, suspension or revocation of an authorization

5.96. The regulatory body should establish procedures for any subsequent amendment, renewal, suspension or revocation of the authorization of a discharge. The date of renewal should be specified in the authorization issued to the operating organization.

5.97. The results of regulatory actions, such as inspections, reviews and assessments, and feedback from operational performance (e.g. feedback on the exceeding of operational limits and conditions or on incidents), should be taken into account in making decisions on the amendment, renewal, suspension or revocation of an authorization.

5.98. The approval of the regulatory body should be obtained before any changes that may significantly affect doses or the safety of operations are made. When such changes may affect the discharges from the facility, the regulatory body should review the authorization for discharges and revise it as necessary. Any changes to authorized discharge limits should be communicated to all interested parties.

INVOLVEMENT OF INTERESTED PARTIES

5.99. Because the regulatory control of radioactive discharges takes into account both operational and societal aspects, such as radioactive waste management in the facility and the optimization of the level of protection of the public, there are a number of different interested parties whose views should be considered, as appropriate. A process resulting in the granting of an authorization for discharges is likely to necessitate an exchange of information between

the regulatory body, the applicant and other interested parties¹⁹. Some interested parties may be located in other States, especially in neighbouring States.

5.100. Any exchange of information relating to the control of discharges may form part of other decision making processes, for example in the context of a governmental decision making process on a major undertaking, such as a decision to construct a large nuclear installation²⁰. Such exchange of information should include consideration of societal aspects, for example, public concern over the risks associated with radiation exposure and consideration of the doses to the public that might result from discharges during operation.

5.101. In some cases, there may be specific requirements for exchange of information with interested parties before the authorization for discharges has been finalized. One means of doing this is through the establishment of a group reflecting local public concerns for liaison both with the operating organization and the regulatory body. Among other things, the results of the prospective radiological environmental impact assessment [7] should be a focal point for the discussions.

5.102. Paragraph 3.124 of GSR Part 3 [3] establishes a requirement to exchange information with other States when a discharge could cause public exposures in these States; for example, if a facility will discharge into an international waterway, or when the representative person is located in a neighbouring State²¹.

6. CONSIDERATION OF EFFLUENTS CONTAINING RADIONUCLIDES OF NATURAL ORIGIN IN DIFFERENT INDUSTRIES

6.1. In general, for facilities and activities authorized in accordance with the requirements of GSR Part 3 [3] there is no distinction in the general approach for controlling the release of

¹⁹ In the context of this Safety Guide, interested parties typically include individuals or organizations representing members of the public, the industry, government agencies or departments whose responsibilities may cover public health, nuclear energy and environment, scientific bodies, the news media, environmental groups [2, 3] and groups in the population with particular habits that may be affected significantly by the discharges, such as local producers and indigenous peoples living in the vicinity of the facility or activity under consideration.

²⁰ DS427 [7] addresses the information relevant for different interested parties, in the framework of governmental decision making and authorization processes relating to facilities and activities.

²¹ Information exchange and, in some cases, consultation with the public and other interested parties is a policy requirement for environmental decisions in some States, for example, for parties to the Aarhus Convention [31].

effluents containing radionuclides of artificial origin or radionuclides of natural origin, for example discharges from nuclear installations and from uranium and thorium mining and processing facilities within the nuclear fuel cycle. This same general approach involves the use of dose limits, dose assessment, dose constraints and optimization of the protection and safety — or best available techniques as relevant — in accordance with the national regulations.

6.2. Some non-nuclear industries may release effluents containing radionuclides of natural origin. In some States, some of these industries involving naturally occurring radioactive material are regulated by national authorities different from the regulatory body and therefore, discharges may not be subject to regulatory control with respect to radioactive substances. Where necessary, the regulatory body should cooperate with other national authorities with responsibilities for the regulation of those industries and should coordinate actions regarding the control of releases, to ensure that radiation protection is taken into account in the management of any effluents²².

6.3. Non-nuclear industries that may generate controlled releases of effluents containing radionuclides of natural origin include onshore and offshore facilities for oil and gas extraction, surface and underground mineral mines, mills and processing facilities outside the nuclear fuel cycle, and the production of rare earth metals, fertilizers, phosphogypsum, thorium, titanium and ceramics using zircon sands. Effluents from the extraction processes used for heavy metals usually also contain naturally occurring radionuclides. Most of the radionuclides of natural origin associated with these industries are found in products, by-products and solid waste. For example, in the phosphate industry, fertilizers contain enhanced levels of uranium, while phosphogypsum waste usually contains enhanced levels of radium. During the production of rare earth elements, radionuclides from the uranium and thorium series are enhanced in the residues.

6.4. Within non-nuclear industries involving naturally occurring radioactive material, atmospheric or liquid releases should be controlled in accordance with the requirements for discharges from planned exposure situations if the activity concentration in the material of any radionuclide in the uranium decay chain or the thorium decay chains is greater than 1 Bq/g or the activity concentration of ⁴⁰K is greater than 10 Bq/g [3]. In cases where the

²² Safety Reports and a Technical Report have been issued on radiation protection and radioactive waste management in industrial activities involving naturally occurring radioactive material (see Refs [32] to [38]).

activity concentrations are below 1 Bq/g or 10 Bq/g, as relevant, the regulatory body may still require an assessment of the doses delivered based on actual exposure scenarios.

6.5. Paragraph I.4 in Schedule I of GSR Part 3 [3] states “For radionuclides of natural origin, exemption of bulk amounts of material is necessarily considered on a case by case basis by using a dose criterion of the order of 1 mSv in a year, commensurate with typical doses due to natural background levels of radiation” [3]. It should be taken into account that the criterion used for exemption of bulk amounts of material containing radionuclides of natural origin is higher than the criterion normally adopted in DS432 [6] and in this Safety Guide for defining the possible range of values for dose constraints for public exposure (i.e. below the dose limit for effective dose of 1 mSv in a year and higher than a dose of the order of 10 μ Sv in a year). This relatively higher criterion for radionuclides of natural origin should be taken into account when dose constraints are specified for these situations, as appropriate. The specification and use of dose constraints is described in Annex I.

6.6. Some important differences that should be taken into account in specifying the operational limits and conditions associated with an authorization for discharges for facilities and activities discharging radionuclides of natural origin or non-nuclear industries releasing naturally occurring radioactive material to the environment, as relevant, are the following:

- (a) The releases are not always from a point source and often occur from large surface areas of stored material. This means that the determination of source terms and dispersion in the environment may be quite difficult and uncertain. For existing facilities, surveys should therefore be conducted to determine the geometry and characteristics of the release (point source versus area source). Alternatively, use may be made of appropriate models for assessing the impact of area sources.
- (b) Greater reliance may need to be placed on environmental monitoring in assessing and verifying doses to the representative person. However, in regions with a relatively high level of natural background radiation, any increment in environmental levels of radiation caused by the discharge may be masked by the natural variability in natural background levels of radiation.
- (c) Specific assessments should be carried out to identify media to be included in the environmental monitoring programme so that any increment in environmental levels of radiation may be followed in time.
- (d) Doses from radon may need to be assessed where large quantities of materials containing uranium or radium are handled or stored, including waste piles. Radioactive

dust may be released through ventilation systems or resuspended from waste piles. In this case, monitoring of radon and dust near venting stacks and waste piles should be performed.

- (e) The cleaning of tanks and pipes, such as those used within some oil and gas industries, that contained residues with elevated levels of radium may result in liquid, aerosol or solid radioactive waste; the need for regulation of such waste should be considered;
- (f) Seasonal variation in rainfall may affect the radioactive releases and the radiological impact of liquid effluents from mining and processing facilities or activities (e.g. where the storage or processing of minerals in open pits is part of the process). For example, in the dry season, the dilution of the releases may be lower and the releases of aerosols and gases such as radon may be higher. Furthermore, sedimentation in periods of low water flow may be followed by remobilization of deposited sediments in periods of high rainfall.
- (g) The hazard associated with the non-radioactive components of the discharge may be more significant than the hazard associated with the radioactive components; in these cases the non-radioactive components of the discharge will normally determine the stringency of the controls to be exercised over the discharge.

The discharge of radionuclides from facilities involving large amounts of naturally occurring radioactive material is the result of a complex interaction of geological, climatic and technological factors. Radiation exposure of members of the public resulting from such discharges involves many exposure pathways, and the level of exposure per unit discharge rate depends on quite a number of site specific conditions. Such site specific conditions can result in very large differences in the dose per unit discharge rate between different sites. Consequently, no simple and general relationship exists between the discharge rate and the effective dose to members of the public. However a detailed site specific analysis is not warranted when, on the basis of a generalized and cautious (conservative) approach, it can be concluded that the discharges are of no radiological significance²³.

²³ Ref. [39] provides information on the use of reference discharge situations for effluents from industries involving naturally occurring radioactive material.

7. CONTROL OF DISCHARGES DURING DECOMMISSIONING

7.1. Decommissioning is a post-operational situation that should be considered as a different practice subject to authorization, requiring specific regulatory provisions [40], including for discharges. In general, two main options for decommissioning should be considered:

- (a) Permanent shutdown of the facility followed by its immediate dismantling; or
- (b) Permanent shutdown of the facility with dismantling deferred to a later date.

7.2. It is typical for effluent discharges to vary through the different phases of decommissioning. For example, as the removal of radioactive hazards progresses through decommissioning, the radioactive discharges may decrease.

7.3. Immediate dismantling of the facility increases the likelihood of mobilizing and potentially releasing radionuclides that may not otherwise have been released. Deferred dismantling will allow time for some radioactive decay to occur.

7.4. The anticipated discharge levels following permanent shutdown of a facility are usually much lower than during the operational period, since any short-lived radionuclides will have decayed. Furthermore, the likelihood of large accidental releases is reduced. However, for some dismantling activities, there may be an increased likelihood of low level unplanned liquid or gaseous releases.

7.5. Whichever of the two main options is chosen, consideration should be given to the following aspects:

- (a) The possibility of additional radionuclides being discharged that were not present in routine discharges during normal operation. For example, alpha emitters, which may not have been present in the discharge during operation, may be discharged when a nuclear installation [is dismantled];
- (b) The need for a survey of these additional radionuclides in the environment to determine pre-existing levels;
- (c) The possibility that any contamination on the site that resulted from incidents during operation may affect the discharges during decommissioning;
- (d) The need to revise the radiological environmental impact assessment, prior to dismantling of the facility, in particular, to determine if new exposure pathways need to be included;

- (e) The need to revise the authorization for discharges, including any conditions relating to the source monitoring and environmental monitoring programmes to take account of any differences identified. The monitoring programmes should be sufficiently robust to detect abnormal or unauthorized discharges;
- (f) The need for more frequent inspections by the regulatory body, particularly while radioactive liquids remain in the facility.

7.6. Dismantling of nuclear installations usually takes place progressively over several years and is usually divided into different stages. Discharges of effluents containing radionuclides typically vary through these steps and the regulatory control should be applied on a case by case basis. Protection and safety should be optimized at each step in the decommissioning process, with account being taken of the experience gained in the previous steps. Because unexpected difficulties and changing conditions may arise during each step, the regulatory control of discharges should reflect the conditions in each step.

8. PREVIOUSLY UNREGULATED PRACTICES

8.1. The regulatory body may identify existing practices or sources that already discharge radionuclides to the environment but not under an authorization as described in this Safety Guide or under less stringent regulations with respect to the control of public exposure. This may be the case for some facilities and activities that are operating prior to the development and full application of the national regulatory infrastructure that meets the requirements of IAEA safety standards [18].

8.2. The regulatory body should, first, establish whether the exposure due to the practice or source may fall within the scope of regulatory control (i.e. whether or not it is excluded from the application of safety standards). If the exposure is not excluded, the regulatory body should determine whether the provisions for exemption of the practice can be applied.

8.3. If authorization for discharges is necessary, as for a new practice, discharges should be adequately characterized, exposure pathways should be identified and a prospective radiological environmental impact assessment should be carried out [7], and a process for defining discharge limits as part of the authorization for discharges should be conducted.

8.4. The applicability of dose constraints to this previously unregulated source should be established. Dose constraints for new practices should not be used without proper consideration for previously unregulated practices because, in a strict sense, dose constraints

apply only prospectively. However, the regulatory body may choose also to establish dose constraints for future operation of an existing practice.

8.5. In any case, the operating organization should be required to demonstrate that the dose in a year to the representative person from all sources is below the effective dose limit of 1 mSv. Furthermore, consideration should be given to whether protection and safety can be further optimized.

8.6. Exceptionally, if the assessed annual dose is found to be greater than 1 mSv, the regulatory body should consider setting authorized discharge limits and operational conditions to ensure that the average annual dose over a five year period is not more than 1 mSv and that the maximum annual dose is lower than 5 mSv in any single year. During this period in which averaging of doses is applied, investigations should be carried out to determine how the discharges can be reduced so that, within a few years, the dose to the representative person is below the annual limit of 1 mSv. The authorization should subsequently be reviewed after this period and the regulatory body should consider withdrawing the authorization for discharges or revising the limits and conditions.

8.7. The limits on effective dose to the representative person should be applied only to future discharges from the facility. They should not take into account the total dose resulting from past unregulated operations of the facility. If appropriate, the contributions to the effective dose from past operations should be addressed within a framework of remedial actions for an existing situation [3].

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Annex I

PRACTICAL CONSIDERATIONS IN GRANTING AN AUTHORIZATION FOR DISCHARGES

SPECIFICATION AND USE OF CONSTRAINTS

I-1. Dose constraints for public exposure in planned exposure situations are required to be set or approved by the government or the regulatory body [I-1]. Dose constraints are set for the specific facility or activity; however national authorities may develop generic dose constraints for facilities or activities with similar characteristics. In some cases, the applicant for an authorization for discharges proposes a dose constraint for a particular facility and activity, which needs to be defensible, discussed with the regulatory body and agreed in a timely manner by the regulatory body.

I-2. In order to establish a generic dose constraint, the regulatory body may consider previous IAEA guidance that suggested 0.3 mSv committed in a year as an appropriate default value, on the basis of maximum levels of individual exposures generally used for optimization in nuclear fuel cycle facilities in various countries²⁴. The ICRP has not explicitly recommended a dose constraint for the control of discharges to the environment, but has also suggested a value of 0.3 mSv per year in relation to disposal of radioactive waste and prolonged exposures (see Refs [I-2, I-3, I-4] and table 8 of Ref. [I-5]). In the requirements for disposal of radioactive waste, a dose constraint of 0.3 mSv per year for optimization of the protection of the public is established, to be used in the design, construction, operation and closure of a disposal facility [I-6].

I-3. When setting a specific dose constraint for a particular activity or facility, the characteristics of the site and of the facility or activity that are relevant for public exposure, good practices and experience in the operation of similar facilities or activities, the location of the facility or activity, dose contributions from other authorized practices and foreseeable future practices and the expected exposure conditions need to be considered. Other factors, such as economic and societal factors, as well as the views of interested parties, would also need to be taken into account.

²⁴ INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Control of Radioactive Discharges to the Environment, IAEA Safety Standards Series No. WS-G-2.3, IAEA, Vienna (2000).

I-4. When considering the contribution to the exposure of the public from other authorized sources of radiation, local and distant practices, as well as existing and projected practices, need to be considered. For example, for a nuclear installation, other nuclear installations co-located on the same site or discharging to the same body of water (particularly rivers and small lakes) could contribute to the exposure of the representative person under consideration; for hospitals in urban areas, other sources of radiation from other practices in the same area (for example, industrial applications and other medical applications) can contribute to the exposure. On the other hand, in the case of practices in remote areas (e.g. uranium mining and processing), the assumption that additional local sources of radiation contribute to the dose may not be appropriate.

I-5. In the case of sites with multiple facilities or facilities and activities in an area where more than one source is present that could contribute to the exposure of the representative person, the specific dose constraint may need to be set at an appropriately low value. On the other hand, for individual facilities or activities located in extremely remote areas, e.g. a uranium mine, it may be reasonable to assume that there are no other contributing sources and, consequently, a higher specific dose constraint could be set.

I-6. Considering that the dose constraint is not set only to take account of other existing or planned sources of exposure to the public, but to guide the optimization of protection for each specific facility or activity, in the case of multiple facilities or activities on the same site it may not always be appropriate to apportion the generic dose constraints by dividing exactly by the number of facilities. A specific dose constraint needs to be assigned to each facility or activity on the basis of its particular contribution to the exposure of the representative person, to ensure that, once the protection is optimized with respect to each source, the resulting combination of doses does not exceed the dose limit.

I-7. In the case of a hospital discharging radionuclides to the sewerage system, the specific dose constraint value may need to be set to take account of the exposure conditions of workers²⁵ at a sewage treatment works used to collect and process liquid discharges from the hospital and from other hospitals using the same treatment facility.

I-8. As described in previous paragraphs and in Section 5, there are different aspects to be considered and different options for specifying discharge limits that can optimize the level of

²⁵ Such workers are not normally monitored for occupational exposure and are subject to the dose limits for public exposure (see GSR Part 3 [I-1], para. 3.78); the representative person may be such a worker.

protection of the public; these may include using best available techniques (see para. 5.39), possibly in combination with application of a dose constraint. States may adopt such different options for optimization of protection subject to national regulations, as far as is consistent with the concept of ensuring that the sum of doses from planned operations for all sources under control remains within the dose limit.

I-9. A scheme illustrating the possible use of a generic dose constraint and specific dose constraints in establishing discharge limits is presented in Figs I-1 and I-2 below. The generic dose constraint is to be set below the dose limit of 1 mSv in a year and above a dose of the order of 10 μ Sv in a year. Figure I-1 illustrates that the specific dose constraint for a facility or activity could be higher or lower than the generic dose constraint, depending on different factors determining the exposure conditions at the location of the representative person, such as the presence of other sources of radiation that can contribute to the dose to the representative person, if relevant.

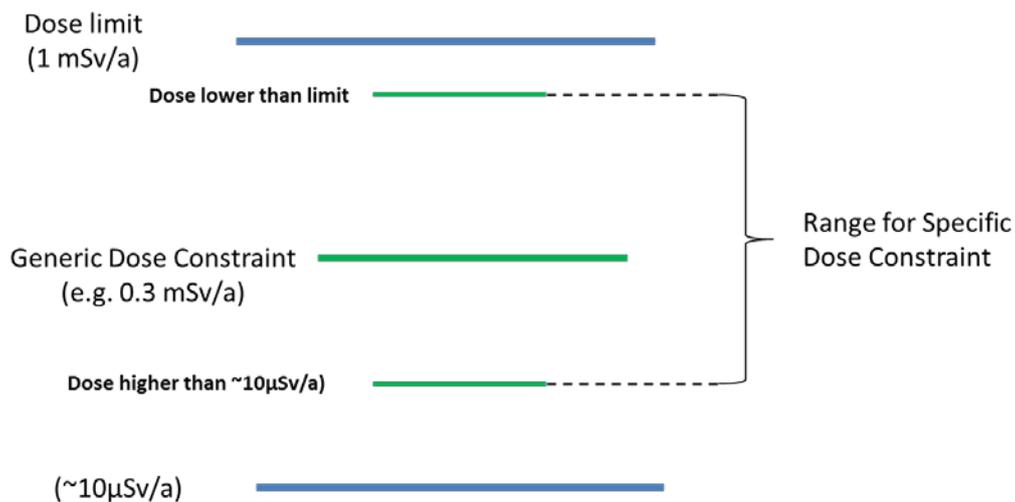


FIG. I-1. Relation between a generic dose constraint and a specific dose constraint.

I-10. Figure I-2 illustrates how a specific dose constraint set for a facility or activity is used as a starting point within the process of optimization to find a level of discharges that is optimal in terms of protection of the public. A margin for operational flexibility needs to be allowed, depending on the characteristic of the activity and facility and their operational features. The dose corresponding to the discharge limit is set below the specific dose constraint and slightly above the dose to the public in accordance with which protection is

considered optimized. The margin for flexibility needs to be determined on the basis of the characteristics of the facility or activity influencing the discharges and may be proposed by the applicant and is subject to approval by the regulatory body.

I-11. Figure I-2 also indicates with an arrow the region below the specific dose constraint that is considered for the optimization process, in which best available techniques could also be used to find the optimal discharge limit. Optimization and best available techniques are addressed below.

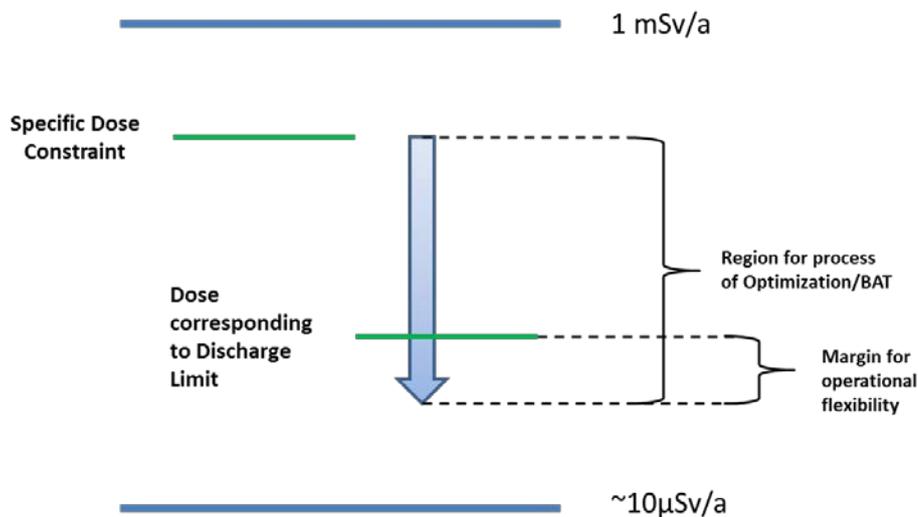


FIG. I-2. Dose to be used for setting discharge limits.

I-12. I-12. Considering the technical characteristics of certain facilities and activities with respect to retention of radionuclides (for example, high efficiency containment and filtering systems in nuclear installations such as nuclear power plants) and, particularly when best available techniques for the confinement and abatement techniques for radionuclides are used, it is possible that the estimated discharges result in assessed doses below the order of 10 µSv per year. In such cases, the regulatory body could consider not requiring that a formal process of optimization, as described in Section 5, be applied.

OPTIMIZATION

I-13. The extent to which a formal process of optimization is applied depends upon the operational status of the facility involved and the doses and risks that could potentially be involved. As described in Section 5 in this Safety Guide, many options for minimizing discharges may lead to increased generation of solid radioactive waste and a corresponding

trade-off between reduced public exposures and reduced occupational exposures. There could also be safety considerations, such as an increased risk of accidental spillages or releases from storage tanks [I-7].

I-14. Different considerations will also be involved in the optimization of protection and safety for proposed and existing facilities or activities. The design stage of a new facility or activity is likely to involve complex technical decisions that may require formal decision aiding techniques to be used. At this stage, there may be a broad range of possible designs and there is the potential for designing the facility such that waste and discharges arising from its operation are reduced, thereby reducing both occupational exposure and public exposure. However, during the operational stage, the options for reducing public exposures are more restricted than during design, owing to the more limited possibilities of introducing changes in the systems and processes for reducing radioactive waste and effluents. Optimization of public protection for ongoing discharges is often undertaken by considering the configurations of the available technical options and the associated procedures, based on the operational experience, in an interactive manner between the regulatory body and the operating organization [I-8].

I-15. Consideration of management options for radioactive waste and effluents includes the evaluation of requirements for design and operational features, storage and treatment (including radionuclides abatement techniques), and prevention of spills. For new facilities protection and safety can be optimized through the design. Before decommissioning is commenced, protection and safety can be optimized through the selection of appropriate options for decommissioning. In the operational and decommissioning stages of the facility there may be fewer options available to optimize protection and safety. However, during operation there may be opportunities to review options for the management of discharges. The management option may then consist of reconfiguring the storage and radionuclide abatement systems of the facility, or back-fitting or upgrading the existing system features. Possible abatement techniques for removal of radionuclides and control methods for effluents are described elsewhere [I-8].

I-16. Different decision aiding techniques may be employed to facilitate the optimization process. The most common decision aiding techniques addressed in the literature are cost benefit analysis and multi-attribute analysis, although other techniques also exist. Information on decision aiding techniques is provided in Ref. [I-9] and further information is given in Ref. [I-8] in relation to the control of discharges

I-17. There are a number of societal and economic factors that may influence the decision on the optimized level of discharge. The effects on future generations, the ability to control exposures, the amount of information available for making informed decisions, and the views of interested parties may also be considered. The need to accommodate and balance the requirements of different strategies also needs to be considered (for example, the requirements to reduce discharges, with associated requirements for waste treatment measures that will increase the generation of solid waste, and the principle of waste minimization).

I-18. Societal and economic factors that need to be considered are dependent on the characteristics of the activity or facility under consideration and site specific attributes, and also on the political and social pressures within a State. A list of such considerations is provided in Ref. [I-8].

I-19. An important aspect that has to be taken into account is international obligations of the State established through binding regional and international conventions relating to the protection of people and protection of the environment. Conventions for prevention of marine environment pollution, such as the Convention for the Protection of the Marine Environment of the North-East Atlantic (the OSPAR Convention), the Convention on the Protection of the Marine Environment of the Baltic Sea Area and the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (the London Convention), may impose additional requirements that have to be included as part of the optimization process. For example, Contracting Parties to the OSPAR Convention are committed to apply best available techniques and best environmental practice including, where appropriate, clean technology, in their efforts to prevent and eliminate marine pollution due to discharges from land based installations [I-10].

USE OF BEST AVAILABLE TECHNIQUES

I-20. When properly specified, the use of best available techniques is an effective approach to optimization that focuses on techniques and technology for protection. The ICRP recognizes that for the control of radioactive emissions to the environment, best available techniques not entailing excessive cost may be used [I-7].

I-21. Within the context of the European Directive on integrated pollution prevention and control [I-11]²⁶, the term ‘best available techniques’ is defined as follows:

- ‘best’, as used in relation to techniques, means the most effective in achieving a high general level of protection of the environment as a whole;
- ‘available techniques’ means those techniques developed on a scale that allows implementation in the relevant class of activity under economically and technically viable conditions, taking into consideration the costs and advantages, whether or not the techniques are used or produced within the State, as long as they are reasonably accessible to the person carrying out the activity;
- ‘techniques’ includes both the technology used and the way in which the installation is designed, built, managed, maintained, operated and decommissioned.

CHARACTERIZATION OF DISCHARGES

I-22. As outlined in paras 5.20 to 5.24 of this Safety Guide, once the need for an authorization has been confirmed, the applicant should characterize the nature of the discharges. For instance, this would be in terms of:

- (a) The industrial process or activity and assumptions made about the discharges it generates;
- (b) The radionuclide composition;
- (c) The chemical and physical form of the radionuclides (related to behaviour in the environment);
- (d) Routes of discharge and discharge points, including aspects such as stack height, exit velocity, exit temperature, maximum and average discharge rates;
- (e) The total amount of the various radionuclides expected to be discharged in one year;
- (f) Expected time pattern of discharge, including the need for and likelihood of increased short term discharges if a constant release rate cannot be assumed.

²⁶ The European Commission has developed a series of reference documents on the application of best available techniques to specific industries, which provide information on relevant techniques, processes used, current emission levels, techniques to consider in determining best available techniques and emerging techniques. See <http://eippcb.jrc.ec.europa.eu/reference/>.

I-23. For existing regulated facilities, information on the characteristics of actual discharges will already exist as a result of the monitoring programmes and these may be considered to support the process of periodic safety review [I-8]. For new or previously unregulated facilities, it may be possible to characterize the discharges on the basis of knowledge of similar facilities elsewhere or engineering analysis. In either case, it is generally necessary to understand the way in which particular effluents are produced to determine the relationship between the discharges and operational parameters, such as energy production figures for nuclear power plants, and the possible effect that waste treatment or waste abatement techniques may have on the amount discharged.

FORMS OF THE AUTHORIZATION FOR DISCHARGES

I-24. There are a number of ways in which authorized discharge limits can be set, based on limiting either the dose to the representative person, the amount of radionuclides discharged or the activity concentration in the liquid and gaseous effluents²⁷. In most cases, the choice is a matter of preference and practicality on the part of the regulatory body, as well as the manner in which the regulatory body requires the licensee to demonstrate compliance.

I-25. Some regulatory bodies prefer to express the limit in terms of a dose, because it relates directly to the actual radiological impact and makes evident the objective of the system of limitation of discharges. Setting limits in terms of amounts of activity or activity concentration of radionuclides to be discharged, on the other hand, is viewed by other regulatory bodies to reflect more closely the quantity that is to be controlled and measured, and is therefore more closely connected to the actions that the operating organization needs to take to control discharges.

I-26. Expressing limits in terms of a dose (i.e. in mSv per year) or an amount of activity or activity concentration of the radionuclides discharged (e.g. Bq per year or Bq/L) does not represent a fundamental difference. The use of either approach is justified because a dose to the representative person and an amount of radionuclides (or activity concentration) are broadly proportional, and one can be converted to the other without difficulty. However, while an amount or a concentration of radionuclides is a directly measurable quantity, the dose to members of the public is always based on an assessment [I-8].

²⁷ In the case where discharge limits are set in terms of activity concentration, this has to be related to a total activity or a total volume of the effluents for a given period, usually per year.

Grouping of radionuclides

I-27. When discharge limits are specified in terms of the quantity of radionuclides discharged, separate limits are usually specified for different radionuclides. Exceptions are cases in which the facility discharges only a few radionuclides, such as a hospital using only iodine or Tc-99m. For most facilities and activities a mixture of radionuclides is discharged. In such cases, it is unusual to set limits for each individual radionuclide, because such an approach is considered cumbersome and unnecessary; instead one limit for a group of radionuclides may be used. Factors influencing the choice of radionuclide groups include: the feasibility of measuring one or more radionuclides within the group; their use as indicators of the performance of the facility; and their contribution to the dose to the representative person.

I-28. For larger facilities that discharge a variety of radionuclides, limits are generally imposed on groups of radionuclides that share similar characteristics, although limits may also be imposed on specific radionuclides that are deemed to be of special significance. Guidance on the grouping of radionuclides is provided in paras 5.70 to 5.72. Tritium and C-14 are of special significance and should be considered for specific limits and consideration (see para. 5.69).

I-29. Grouping of radionuclides is appropriate in situations in which members of some radionuclide groups are usually discharged in fairly fixed proportions, and therefore the occurrence of one radionuclide indicates the presence of the others in the group. Such grouping has the merit of simplicity in both the formulation of the limits as well as their application. The radionuclide of the group that is most easily detected at the desired sensitivity is often used in specifying the discharge limit for the group²⁸.

I-30. In some cases, a regulatory body may include in the authorization for discharges limits on specific radionuclides that provide early indications of changes in the operational status of the facility, or that make an exceptionally high contribution to the total dose to the representative person. When limits are specified for groups of radionuclides, the approach is usually to set the limit for the group on the basis of the characteristics of the most radiotoxic radionuclide of the group.

Site specific or facility specific limits

²⁸ Periodic review may need to be undertaken if there is reason to believe that the ratio of the various radionuclides in the group might change.

I-31. Discharge limits may be specified either for the whole site, for each unit within a site, or even for each discharge point, such as a stack or a pipe. A unit in this context means an identifiable entity that generates airborne or liquid waste. For example, at a large hospital, there may be a nuclear medicine facility, a waste treatment facility, and an incinerator, each of which has its own discharge point and each of which may be considered as a separate and independent unit on which discharge limits may be imposed. At a nuclear power plant site, each unit may be a nuclear reactor. In general, the regulatory body will impose discharge limits for each individual unit, but in some cases the regulatory body will impose only a site limit, with no limits for individual units [I-8].

Time interval for demonstrating compliance

I-32. The basic interval over which compliance is expected to be shown is normally one year, usually a calendar year, although a rolling 12 month period is also used. The advantage of the latter approach is that it may permit closer supervision of the facility by the regulatory body, but it is administratively more cumbersome to implement. In some cases the interval can be tied to operating cycles of the activity, which may be longer than one year.

I-33. Although annual discharge limits are almost always used and are considered as the primary means of regulatory control, some regulatory bodies consider the need to establish discharge limits for shorter periods (e.g. on a monthly basis or a quarterly basis). This could be justified if there is concern that the validity of the averaging assumptions used in setting annual discharge limits (e.g. in the estimation of the dose to the representative person) is not applicable if short term increased discharges occur. For such cases, dose assessments using assumptions valid for the shorter periods need to be carried out.

I-34. Parameters used to estimate the doses that form the basis for setting discharge limits are typically chosen to be representative of annual averages. For example, the prevailing wind direction and speed, the stability category of the atmosphere, and the dietary habits assumed are usually annual averages. It is possible that a facility may discharge a significant fraction of its annual allowance over a short period, or a series of short periods. Short term limits are therefore often specified in addition to annual limits. The short term limits also allow the regulatory body to more closely monitor the facility's performance, and to take action if operations fail to meet the short term limits. Short term limits are generally higher than the pro-rated value for the applicable duration, to allow for operational flexibility [I-8].

I-35. Consideration also needs to be given to setting discharge limits for those facilities where total discharges are generally low but where specific events can result in short term discharges

without markedly affecting the long term average discharges, e.g. replacement of the molybdenum generators in a technetium production facility or discharges from hospitals treating patients with radioiodine).

Operational flexibility

I-36. Discharge limits are set by taking account of dose constraints and the need for optimization, so a breach of a discharge limit may not result in a breach of a dose limit; indeed this is the main aim of the regulatory control of discharges. Exceeding discharge limits would normally initiate actions by the licensee and the regulatory body (e.g. a report, an investigation, corrective measures, inspections), even if the resulting doses to the public are assessed to be below the dose limits. To avoid frequent contraventions of regulatory requirements that would result in significant and unnecessary expenditure of resources, negative public perception and frequent interference with the operation of the facility, some margin for operational flexibility may be allowed when setting discharge limits.

I-37. The margin for operational flexibility needs to allow for what would be anticipated under normal operating events [I-8]. Such events include practices or facility conditions that lead to a temporary increase in discharge levels of a relatively short duration, usually hours to days, but which are not considered an abnormal event, such as an increased number of patients in a nuclear medicine department or a temporary failure or loss of efficiency of an effluent treatment system.

I-38. Specific guidance cannot be provided to assist in determining the appropriate margin to allow for operational flexibility. Previous experience with similar facilities can provide useful information on the minimum allowance for flexibility that needs to be permitted, in accordance with the regulatory framework [I-8].

Period of validity of the authorization for discharges

I-39. While in principle the authorization for discharges could have the same validity period as the authorization of the facility or activity, some regulatory bodies issue authorizations for discharges that have a shorter period of validity or specify that the discharge limits are subject to revision within the framework of a periodic safety review. In such cases, at the end of the period of validity, the authorization for discharges is reviewed, and updated, as necessary, on the basis of current information relating to public exposure and operational experience. The usual period for periodic safety review for more complex installations is ten years. The appropriate period is generally selected by the regulatory body based on, for example, the

likelihood of the occurrence of changes at the site and its surrounding environment that may affect the conditions according to which the authorization for discharges was initially issued. Some regulatory bodies may decide to review and update the authorizations at any time if necessary and do not apply a specified limit on the validity of the authorization for discharges.

I-40. Operating organizations are required to obtain approval from the regulatory body before making any changes to the operation of the facility or conduct of the activity that may affect doses significantly or the safety of operations. If a number of changes are made over a period of time there may be a change in the safety performance of the facility or activity that can only be evaluated through a complete review of the overall operation. The period of validity is also influenced by the degree of ongoing review and supervision provided by the regulatory body, and the breadth and depth of such ongoing reviews. In some cases, such ongoing reviews are of such a depth and scope that they constitute, in themselves, a formal review of the authorization for the facility or activity.

I-41. In other cases, the period of validity of the authorization for discharges may be equal to the expected life of the facility or activity. Such practices would normally have stringent ongoing review and audit requirements imposed in their authorization, such as, for example, a requirement that a periodic safety review be carried out irrespective of whether there have been any significant changes in operation or in dose assessment factors such as the demographics and land use in the areas surrounding the facility. This would ensure that the assumptions used to estimate doses to the representative person, such as the source term, the location where the representative person lives, the habit data and other assumptions such as the locations of dairy farms and vegetable gardens, remain valid. Any significant changes are generally required to be reported to the regulatory body, which may decide to initiate a formal review of the authorization for discharges, if relevant.

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CONTRIBUTORS TO DRAFTING AND REVIEW

Asfaw, K.	International Atomic Energy Agency
Berkovskyy, V.	Ukrainian Radiation Protection Institute, Ukraine
Boal, T.	International Atomic Energy Agency
Bonchuk, I.	Ukrainian Radiation Protection Institute, Ukraine
Cabianca, T.	Public Health England, HPE, United Kingdom
Chartier, M.	Institut de Radioprotection et de Sureté Nucléaire, France
Conatser, R.L.	Nuclear Regulatory Commission, United States of America
Dehmel, J.-C.	Nuclear Regulatory Commission, United States of America
Hamlat, M.S.	Canadian Nuclear Safety Commission, Canada
Harman, N.	Consultant, Amec, United Kingdom
Iimoto, T.	University of Tokyo, Japan
Jones, K.	Consultant, HPE, United Kingdom
Kliaus, V.	Republican Scientific-Practical Centre of Hygiene , Belarus
Linsley, G.	Consultant, United Kingdom
Proehl, G.	International Atomic Energy Agency
Robinson, C.	United Nations Environment Programme
Rochedo, E.	Comissão Nacional de Energia Nuclear, Brazil
Simmonds, J.	Consultant, United Kingdom
Telleria, D.	International Atomic Energy Agency
Thompson, P.	Canadian Nuclear Safety Commission, Canada
Walker, J.	Consultant, Canada
Wrixon, A.D.	Consultant, Austria