

DS442

Date: March 2015 (Draft 5)

IAEA SAFETY STANDARDS

for protecting people and the environment

Status: Step 8:

For Member States' review and comments

Deadline for Comments: 20 July 2015

Regulatory Control of Radioactive Discharges to the Environment

DRAFT SAFETY GUIDE

DS442

(Revision of WS-G-2.3)

IAEA

International Atomic Energy Agency

CONTENTS

1. INTRODUCTION	1
BACKGROUND.....	1
OBJECTIVE.....	2
SCOPE 2	
STRUCTURE	3
2. THE PRINCIPLES FOR CONTROL OF DISCHARGES.....	4
JUSTIFICATION	4
OPTIMIZATION.....	4
DOSE LIMITATION	5
3. SAFETY OBJECTIVES AND REQUIREMENTS RELEVANT TO THE CONTROL OF RADIOACTIVE DISCHARGES6	
GENERAL	6
JUSTIFICATION	7
OPTIMIZATION.....	7
AUTHORIZATION	8
DOSE LIMITS.....	9
TRANSBOUNDARY IMPACTS	9
PERIODICAL REVIEW	10
SOURCE AND ENVIRONMENT MONITORING	10
GRADED APPROACH.....	10
4. ESTABLISHING THE NEED FOR A DISCHARGE AUTHORIZATION.....	11
5. AUTHORIZATION PROCESS	13
DEVELOPMENT OF A DISCHARGE AUTHORIZATION.....	16
ESTABLISHING A DOSE CONSTRAINT FOR APPLICATION TO THE CONTROL OF DISCHARGES.....	18
CHARACTERIZATION OF DISCHARGES AND EXPOSURE SCENARIOS	19
CONSIDERATION OF OPTIMIZATION OF PROTECTION	21
ASSESSMENTS OF DOSES TO REPRESENTATIVE PERSON.....	26
AUTHORIZATION OF DISCHARGE AND CONDITIONS.....	29
DEMONSTRATION OF COMPLIANCE	33
INSPECTION AND ENFORCEMENT	36
INVOLVEMENT OF INTERESTED PARTIES.....	37
6. CONSIDERATION OF NATURALLY OCcurring RADIONUCLIDES IN DIFFERENT INDUSTRIES.....	38
7. CONTROL OF DISCHARGES DURING DECOMMISSIONING	41
8. PREVIOUSLY UNREGULATED PRACTICES.....	42
REFERENCES	44
ANNEX PRACTICAL CONSIDERATIONS IN SETTING DISCHARGE AUTHORIZATIONS	47
CONTRIBUTORS TO DRAFTING AND REVIEW.....	61

1. INTRODUCTION

BACKGROUND

1.1. Facilities and activities¹ [1] that use radioactive sources, including nuclear reactors, are required to be designed, built, licensed, operated and maintained in a manner to prevent or minimize radioactive releases to the environment, providing adequate levels of protection for the public and the environment. Some facilities and activities may generate a variety of gaseous and liquid effluents during their normal operation, containing minor amounts of radioactive residues that can produce very low doses to the public. Owing to the low activity concentrations and high volumes of gases and liquid involved, such releases would be in many cases technically difficult or extremely costly to avoid.

1.2. The requirements for optimization of radiation protection may give rise to the conclusion that, if reasonable efforts has been done to maintain those releases as low as achievable, considering social and economic factors, the resulting doses are very low and below the applicable dose constraints, such releases are deemed to be justified from the radiological protection perspective, considering the very low radiological significance and the high unjustified costs which may be involved.

1.3. In these cases it is appropriate to issue a permit to release these effluents to the environment, establishing stringent technical and regulatory conditions, including for the adequate management and control of these effluents and their radiological consequences, prior and after the releases may occur.

1.4. Even though the doses received by the public due to the authorized releases of effluents are very low, they must meet the established dose limits and dose constraint. In accordance with principles and the requirements established in the IAEA safety standards [1, 2], these effluents are required to be properly managed by the licensees, in order to ensure the optimized protection of the public and the protection of the environment, without affecting the adequate level of protection of workers or imposing unnecessary burdens on the responsible organizations operating such facilities or conducting such activities.

¹ 'Facilities and activities' are defined in the IAEA Fundamental Safety Principles [1]. It is a general term encompassing all nuclear facilities and uses of all sources of ionizing radiation. The present guidance is pertinent to certain activities and facilities which are described in the Scope.

1.5. The term ‘discharge’ is used to refer to the on-going or anticipated authorized controllable releases of gaseous, aerosol or liquid radioactive substances to the environment and, as such, does not include accidental releases to the environment. The term discharges 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 or to be released [3].

1.6. Members of the public may be exposed to radiation as a result of such discharges to the environment. According to the IAEA safety standards [2], measures have to be taken to ensure that facilities are operated and activities are conducted in such a way that the highest standards of safety can reasonably be achieved; these measures include the control² of radioactive discharges.

1.7. This Safety Guide is concerned with the application of the safety requirements established in GSR Part 3 [2] to the regulatory control of discharges [4] and takes account of the advice given in a number of relevant Safety Guides [5-11] and experience from IAEA Member States.

OBJECTIVE

1.8. The objective of this Safety Guide is to provide governments, regulatory bodies, applicants, registrants and licensees³, as defined in GSR Part 3 [2], with a structured approach to control the radiation exposures to the public resulting from discharges resulting from normal operations of facilities and activities and for the optimization of protection and safety (for the purposes of the present publication, essentially the optimization of protection). Guidance is given on establishing discharge authorizations, on demonstrating compliance with them and on enforcing them.

1.9. This Safety Guide is for use by those applying for an authorization for discharges to the environment and those reviewing and authorizing them, as part of a regulatory authorization process. It may also be of relevance to other interested parties.

SCOPE

1.10. The scope of this Safety Guide is limited to releases to the atmosphere of airborne (gases and aerosols) or releases to surface aquatic media of liquid effluents from activities and

² The term ‘control’ is defined in [2] and refers to the function or power or (usually as controls) means of directing, regulating or restraining.

³ The term ‘operating organization’ is defined in [3] and encompasses applicants, registrants and licensees.

facilities during normal operations in planned exposure situations⁴. Solid radioactive waste, post-disposal delayed releases, injection of liquids containing radioactive material into underground water, and releases to the environment arising from accidents are not addressed in this Safety Guide.

1.11. This Safety Guide provides guidance on the regulatory control of the discharges in connection with an authorization process⁵. The authorization of discharges from new and modified facilities or activities, together with the review of established discharge authorizations are considered.

1.12. This Safety Guide addresses the derivation of authorized operational limits for discharges, the demonstration of compliance with the authorization and discusses the need for radiological monitoring programmes. An important initial input into the process of controlling discharges is the prospective assessment of the level of protection of public and the environment against the harmful effects of ionizing radiation. A separate Safety Guide considered the requirements for such prospective radiological impact assessments for both the public and the environment [8]. Only limited reference is made in this Safety Guide to the principles underlying dose assessments and the use of assessment models and data that may be used in the derivation of authorized limits, such as those described in references [12, 13], but it does not cover the development of such assessment models and data.

1.13. The facilities and activities considered cover a wide range of radioactive sources. For example, from those used in the general industry, in medicine and research to nuclear facilities like reactors, reprocessing plants and others. This Safety Guide also covers the releases which may result from mining and milling of ores for the extraction of uranium or thorium as part of the nuclear fuel cycle. Consideration is also given to the releases of naturally occurring radioactive substances in non-nuclear or non-radiation-related industries.

STRUCTURE

1.14. Section 2 discusses the principles of radiation protection applicable to the control of discharges. Section 3 presents the safety objectives, requirements and concepts contained in

⁴ A planned exposure situation is defined in [2]. Another word used as a synonymous in this Safety Guide is 'practice' [3].

⁵ The authorization process for facilities and activities, with wider aspects related to safety and protection, is established in GRS Part 3 [2]. The consideration of the assessment of the radiological impact to the public and the environment in the framework of an authorization process is discussed in more details in Ref. [8].

the Safety Standards relevant to the control of discharges including the general responsibilities of governments, the regulatory bodies, registrants/licensees and other relevant parties. Section 4 provides guidance on a decision process to establish the need for a discharge authorization. Section 5 discusses the authorization process, including the development of a discharge authorization (discharge limits), the establishment and use of dose constraints, the characterization of the discharges and the exposure scenarios used to specify the discharge limits, the consideration of the optimization, the assessment of doses to the public, the conditions in the authorization, the compliance and the involvement of interested parties. Section 6 covers the particularities of facilities and activities with naturally occurring radionuclides. In Section 7 the aspects related to control of discharges during decommissioning are presented. Finally, Section 8 discusses how to consider previous unregulated practices. An Annex provides practical considerations to be taken into account when setting the discharge authorizations.

2. THE PRINCIPLES FOR CONTROL OF DISCHARGES

2.1. The radiation protection principles adopted in the IAEA Safety Standards [1, 2], on the basis of the definitions by ICRP [14], that should be used to control radioactive releases to the environment from a facility or activity in planned exposures situations are those of justification, optimization and dose limitation.

JUSTIFICATION

2.2. In order to consider the authorization of an activity or facility it should be demonstrated that the introduction of that practice will produce a positive net benefit e.g. the expected benefits to individuals and society from the practice should outweigh the harm, including the radiation detriment.

2.3. Justification applies to the overall practice and not to individual components such as discharges which can only be authorized (or exempted from the authorization requirement) if the practice as a whole has already been regarded as justified.

OPTIMIZATION

3.1. The principle of optimization of protection and safety, which is defined as “the process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to

exposure and the likelihood of exposure being as low as reasonably achievable, economic and social factors being taken into account” [2], should be applied when setting discharge limits.

3.2. The protection and safety measures should provide the highest level of safety that can reasonably be achieved throughout the lifetime of the facility without unduly limiting the operation of the facility. The optimization of protection and safety involves the balancing of costs, not just financial, of 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 given in Section 5 of this Safety Guide

DOSE LIMITATION

3.3. The dose limits for members of the public in planned exposure situations are [2]:

- (a) An effective dose of 1 mSv in a year;
- (b) In special circumstances⁶, a higher value of effective dose in a single year could apply, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year.
- (c) An equivalent dose to the lens of the eye of 15 mSv in a year;
- (d) An equivalent dose to the skin of 50 mSv in a year.

These dose limits represent the maximum acceptable dose to members of the public in planned exposures situations and include all the sources of radiation. The discharge limit for a specific source should be set accordingly (this is discussed in Section 5).

⁶ For example, in authorized operational conditions that leads to transitory increases of exposures.

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

GENERAL

3.1. The Fundamental Safety Principles [1] establish, among others, principles for ensuring the protection of the public and the environment, now and in the future, from harmful effects of ionizing radiation. The fundamental safety objective is to protect people and the environment 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.

3.2. The requirements for a governmental, legal and regulatory framework for safety are established in GSR Part 1 [15] and it is assumed in this Safety Guide that these requirements have been fulfilled.

3.3. GSR Part 3 [2] discusses the concepts and establishes requirements for the protection of people and the environment from harmful effects of ionizing radiation and for the safety of radiation sources. It includes requirements for the control of discharges of relevance to the various interested parties (such as government, regulatory bodies and operating organizations).

3.4. GSR Part 3 specifies the system of protection and safety with the aim 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 [2]. For planned exposure situations, GSR Part 3 states that exposures and risk 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 [2].

3.5. The system of protection and safety required by the IAEA Safety Standards, which is founded primarily on considerations of people radiological protection, generally aims to provide for appropriate protection of the environment against harmful effects of radiation [2].

3.6. The establishment of discharge limits for facilities and activities, as described in this Safety Guide, is based on the optimization of the protection of members of the public (e.g. the

endpoints of the assessment to specify discharge limits is dose to the representative person⁷). This approach assumes that the environment is protected by mean of the conditions resulting in the authorization for the practice⁸.

JUSTIFICATION

3.7. Paragraph 2.8 of GSR Part 3 [2] state: “For planned exposure situations, each party with responsibilities for protection and safety shall ensure, when relevant requirements apply to that party, that no practice is undertaken unless it is justified”.

3.8. Requirement 10 of GSR Part 3 [2] states: “the government or the regulatory body shall ensure that only justified practices are authorized”.

OPTIMIZATION

3.9. Requirement 31 of GSR Part 3 [2] 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 [2] establishes a number of requirements for the handling of radioactive waste, notably including the requirement to ensure that waste is ‘kept to the minimum practicable in terms of both activity and volume’.

3.11. Paragraphs 3.119 and 3.120 in GSR Part 3 [2] specify that “the government or regulatory body shall: (a) establish and enforce requirements for the optimization of protection and safety for situations in which individuals are or could be subject to public exposure’. (b) establish or approve constraints on dose and on risk to be used in the optimization of protection and safety for members of the public”.

⁷ An (hypothetical) individual, for the purpose of radiation protection, receiving a dose representative of the more highly exposed individuals in the population. In relation to control of discharges the representative person can be considered to be the same concept of the critical group and similar methods can be used to assess doses to the representative person that were used previously for the critical group [14, 16].

⁸ Some States may consider that, in addition to the optimization of the protection of the public and the assumption that in doing that the environment result also protected, there may be a need to assess more explicitly the protection of the environment, including, for instance, estimations of radiation exposure of populations of flora and fauna. In general, consideration of the exposure of flora and fauna is not necessary when setting discharge limits, because human exposure due to radioactive substances the environment is the more restrictive factor. Exposures to flora and fauna can be done in the framework of environmental impact assessments. Ref. [8] provides guidance on radiological environmental impact assessment.

3.12. Para. 3.22 of the GSR Part 3 [2] states: “the government or 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 [2] states: “the government or regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized”.

3.14. In applying the principle of optimization of protection and safety in relation to public exposure Requirement 30 in GSR Part 3 (paragraph 3.126) [2] specifies that the following should be taken into account:

- (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 build up 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 [2] lays down requirements regarding discharges that underpin the guidance given here. 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 exposures of members of the public;
- (c) Shall assess 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) to (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. GSR Part 3 [2] also lays down the following requirements related to the control of discharges (para. 3.123): “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 impacts⁹ that is undertaken in accordance with national requirements of the regulatory body”.

DOSE LIMITS

3.17. Requirement 12 of GSR Part 3 [2] states: “the government or regulatory body shall establish dose limits for ... public exposure, and registrants and licensees shall apply these limits”. Para. 3.26 goes on to state: “the regulatory body shall enforce compliance with the dose limits ... for public exposures in planned exposure situations”.

TRANSBOUNDARY IMPACTS

3.18. The GSR Part 3 also lays down requirements to the regulatory body for the assessment of 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

⁹ Guidance on prospective radiological environmental impact assessment which should be used as an input to the establishment of discharge limits is provided in Ref. [8].

of control of the State in which the source is located' (GSR Part 3 paragraph 3.124). In that situation, the radiological impacts outside the national territory must be included in the assessments, the control of discharges shall be established considering those impacts and means for the exchange of information and consultations, as appropriate shall be arranged with the State(s) where exposures are expected [2].

PERIODICAL REVIEW

3.19. The GSR Part 3, paragraph 3.134 [2], also gives requirements that “registrants and licensees shall review and modify their discharge control measures” taking into account: “operating experience” and “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 AND ENVIRONMENT MONITORING

3.20. There is also a requirement on the regulatory body and relevant parties to ensure that programmes for source monitoring and environmental monitoring are in place (Requirement 32 of the GSR Part 3 and para. 3.135 [2])¹⁰. The programmes shall 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 radiological environmental impacts’.

3.21. Registrants and licensees are required by para. 3.137 of GSR Part 3 [2] 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.

GRADED APPROACH

3.22. The specific requirements relating to a graded approach are given in GSR Part 1 [15], GSR Part 3 [2] and GSR Part 4 [17]. In relation to the control of discharges, the graded

¹⁰ Guidance on source and environmental monitoring which should be used to defining the monitoring programmes related to public exposure control is provided in Ref. [8].

approach should be reflected in the application of the requirements of the GSR Part 3 in planned exposure situations (Requirement 6 of Ref. [2]), e.g. that the resources devoted to assess and control discharges and the scope and stringency of the regulations must be commensurate with the magnitude of the radiation risk and their amenability to control.

4. ESTABLISHING THE NEED FOR A DISCHARGE AUTHORIZATION

4.1. Authorization of discharges should not be applied to practices where the radiological impact to the public is deemed to be not amenable to control (e.g. when dealing with radiation sources which are excluded from the IAEA safety standards as stated in [2]; for example releases of naturally occurring radioactive materials at its original levels or when the radiological impact is below the criteria for exemption as established in [2]¹¹. The regulatory body should specify when the discharges are excluded¹² or exempted.

4.2. In order to decide whether a discharge authorization is required key factors are that the overall practice should be justified and then whether the practice can be excluded or exempted from regulatory control. Figure 1 illustrates a scheme to decide whether a discharge authorization is required.

4.3. Paragraph I.2 in the Schedule I in GSR Part 3 [2] indicates that an effective dose of the order of 10 μ Sv in a year received under all reasonably foreseeable circumstances would imply no need of an authorization. To take into account low probability scenarios, a different criterion could be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

¹¹ The criteria for exemption are specified in Schedule I of the GSR Part 3 [2]. Information is also provided on levels of activity and activity concentrations of a large number of radionuclides to assist with exemption of moderate amounts of materials and bulk amounts of solid materials. However, those levels are not intended for and should not be applied to the control of discharges.

¹² The regulatory body should consider the incorporation of historically excluded practices on the basis of the radiological impact to public.

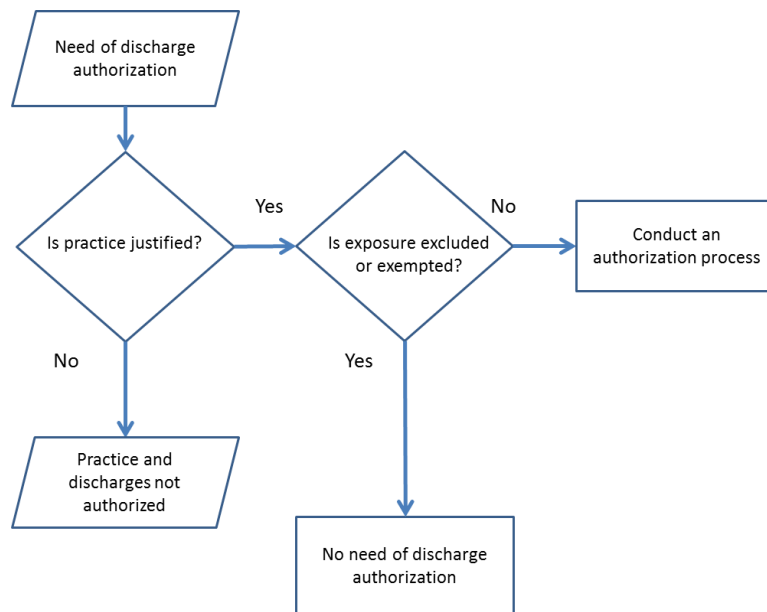


FIG. 1. A decision process to determine the need of a discharge authorization.

4.4. Exemption may be given generically or on a case-by-case basis. If given generically, the regulatory body should provide the conditions for exemption in a regulatory document which should be made available. It should be noted that exemption operates within the regulatory system and the provisions for exemption may be amended by the regulatory body, if this is subsequently shown to be necessary. Examples of candidates for exemption are discharges from research laboratories using small quantities of radionuclides in tracer studies or in radioimmunoassay techniques and hospitals using xenon test kits. In such cases, no discharge authorization need be developed and simple checks could be made on the discharge levels, for example, from estimates of activity balance.

4.5. Notification alone should only be used when the assessed doses are low and the regulatory body does not consider exemption to be appropriate. Notification makes the regulatory body aware of the discharges and provides the opportunity for the regulatory body to keep them under review. As with exemption, simple checks could be made on discharge levels, for example, from estimates of activity balance. If notification alone is to be used, the regulatory body should consider developing clear criteria for this relating to such things as the radionuclides and the maximum activities that can be discharged in a given time period.

5. AUTHORIZATION PROCESS

5.1. 'Authorization' is a term defined in the GSR Part 3 [2] and is a formal process established in the national regulatory framework by which a regulatory body or other governmental body grants written permission, at different stages of the lifetime of a facility or to conduct an activity.

5.2. The control of discharges is one aspect of the authorization process and although some consideration would be given to this throughout the lifetime of the facility, more detailed consideration of the authorization of discharges would be limited to particular stages. Therefore, the control of discharges is more relevant to some of these stages than others.

5.3. The regulatory body should specify the authorization process for facilities and activities, including the provisions for discharges, using the concept of a graded approach. Ref. [8] provides guidance on different factors which should be considered to characterize simple or complex practices, according to the expected level of radiological impact to public and the environment.

5.4. For simple facilities or activities, like those with limited amounts of radionuclides with potential to be released to the environment, the authorization process should normally consist of one stage.

5.5. For complex facilities, like nuclear facilities, there may be multiple stages for the full authorization process which are associated with different phases of the lifetime of the facility: from siting and site evaluation to decommissioning, and release from regulatory control. Figure 2 (adapted from Ref. [18]) describes schematically the stages in the lifetime of a complex facility, like a nuclear installation, and the timing when the control of discharges should be considered.

5.6. During the siting, design and construction phases the applicant should provide information relevant to the optimization of the protection of the public to the regulatory body, for instance possible discharges to atmosphere and to surface water bodies and its radiological impact on the public and the environment, generation of waste, and waste management and its impact to workers. This information should be sufficient to allow the regulatory body to form an opinion about the suitability of the optimization procedure. In some circumstances a provisional discharge authorization could be issued before construction starts.

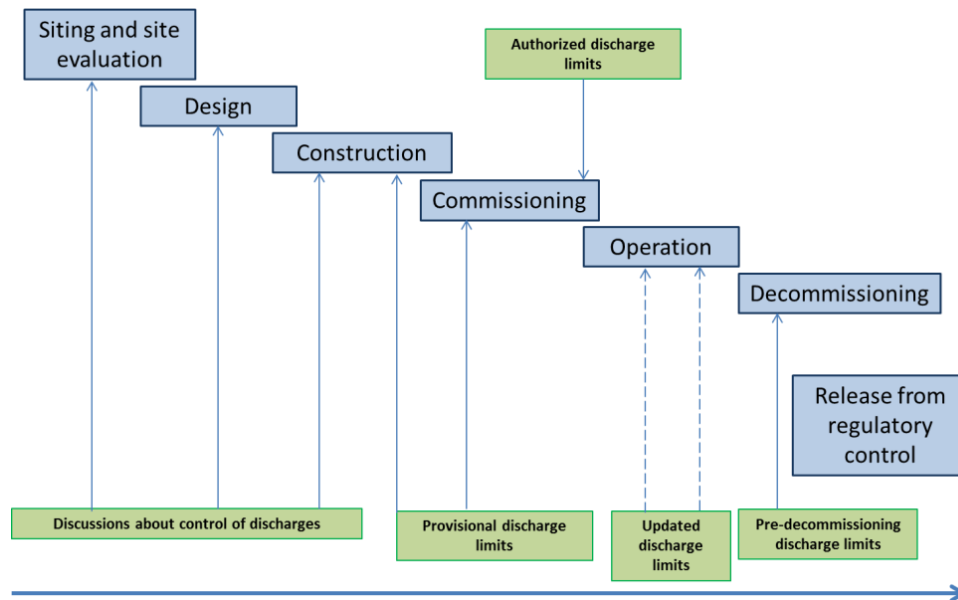


FIG. 2. Example of stages in the lifetime of a facility and the timing when the control of discharges should be considered.

5.7. GRS Part 3 requires that for setting discharge limits, the results of radiological environmental impact assessments conducted in accordance with the requirements of the regulatory body shall be considered. Guidance on prospective radiological environmental impact assessment for facilities and activities which should be conducted during or prior to siting, design and construction phases is presented in Ref. [8]. Because the aim of the radiological environmental impact assessment is to obtain a comprehensive anticipated view of the risk to public of the environment represented by the facility or activity, radiological environmental impact assessments include more aspects than the impact to members of the public during normal operations, which are the basis for establishing discharge limits. For example, they also include the consideration of potential exposures due to the conceivable accidents resulting in safety assessment studies. The results of such prospective assessment should be compared to relevant criteria and this will give the first indication of the acceptability of the facility or activity under consideration and provide useful information to be considered during the optimization of the protection of public and subsequent process of setting discharge limits.

5.8. At a later state, for instance in the commissioning stage, further detailed information should be provided to the regulatory body so that it is sufficient to make judgements to set a full discharge authorization at the end of the commissioning stage, before the start of operation. The procedure to develop a discharge authorization, including the information that

should be required by the regulatory body to the applicant is described in the following Section, paragraphs 5.x to 5.y (Note: exact paragraphs to be indicated at the end of edition).

5.9. During the operation phase the discharge authorization should be reviewed, as part of the periodic safety review [2]. Significant changes in any condition that could affect public exposure should be taken into account during the review of an existing authorization. For example, significant changes could be those in the characteristics and operation of the source, changes in the conditions of discharges, changes in exposure pathways, changes in the habits or distribution of the population or changes in the environmental dispersion conditions.

5.10. A new discharge authorization should be required when operation concludes to take account of the likely changes to the discharges during the decommissioning process. This authorization should provide the new discharge limits prior to the start of the decommissioning activities. In some situations, operation and decommission activities may be overlapping, needing consideration in the authorization of the relevant discharge limits.

5.11. When an activity or facility is released from regulatory control after decommissioning, normally the resulting exposure scenario to public, after fulfilling the relevant criteria, implies that a discharge authorization is no longer required. However some practices like mining or milling of uranium, after decommissioning could need a certain form of control of the public exposures due to residual releases to the environment that may still occur. For these situations, the regulatory body should specify the control needed after decommissioning on the measures to prevent public exposure and, when relevant, the necessary environmental monitoring programme on a case-by-case basis.

5.12. A graded approach should be applied to all stages of the authorization process. Authorization can be by means of registration or licensing. Depending on national arrangements, the choice should depend on the level of dose associated with the facility or activity and the likelihood of releases and possible consequences of releases of radioactive material to the environment.

5.13. Authorization through registration should be used where:

- (a) safety can largely be ensured by the design of the facilities and equipment;
- (b) the operating procedures are simple;
- (c) the safety training requirements are minimal; and
- (d) there is a history of few problems with safety in these types of operation.

Registrations are usually expressed in somewhat generic terms but may have specific conditions or limitations attached. Registration is best suited to those practices for which the risk of exposure is very low and operations do not vary significantly. The regulatory body should specify the practices which may be authorized through registration.

5.14. Licensing should then be applied in all other cases, with the stringency of the conditions graded according to the level of risk. The regulatory body should establish the required level of stringency of the conditions in the discharge authorization taking into account the likelihood and expected magnitude of exposures, the characteristics of the facility and a number of additional factors like, the characteristics of the source term, the level of expected doses, the safety characteristics of the activity or facility and the characteristics of the location.

DEVELOPMENT OF A DISCHARGE AUTHORIZATION

5.15. A graded approach should be used when considering radioactive discharges. Consequently, the guidance on the setting of authorized limits is given for different types of facility and activities that may discharge radionuclides into the environment. This includes simple facilities, for instance hospitals with small nuclear medicine departments and small research laboratories, and those more complex installations such as nuclear power and reprocessing plants, large laboratories, production of radioisotopes facilities and certain activities which may release radionuclides to the environment in a controllable manner for some parts of the processes being conducted, like uranium mining and processing. The special characteristics to be considered regarding discharges of naturally occurring radionuclides from non-nuclear industries are discussed in Section 8 below. Additional explanation of the authorization process for nuclear installation may be found in Ref. [5] and [8].

5.16. The regulatory body should establish the process to be followed by the applicant seeking a discharge authorization. The decision on the need for a discharge authorization was discussed before in Section 4.

5.17. Once the need of a discharge authorization was confirmed, the steps of the authorization process should be as follows:

- (a) The regulatory body should identify or specify the relevant dose constraint for the facility or activity under consideration (this is more discussed below and in the Annex).
- (b) The applicant should characterize the discharges and the main exposure pathways identified, in order to assess adequately the exposures to the representative person.

- (c) The applicant should carry out the optimization of protection of the public, considering measures to be used to minimize the discharges taking into account all relevant factors¹³.
- (d) The applicant should assess the doses to the representative person (this may involve starting with a simple cautious generic assessment and, if required, a more detailed and site-specific study).
- (e) The applicant should submit the results of the assessment to the regulatory body. The regulatory body should evaluate if the models and assumptions used by the applicant are valid and if the resulting doses provides optimized protection of the public.
- (f) The regulatory body should establish conditions for the authorization and any arrangements for demonstration of compliance during operation, including source and environment monitoring systems and programmes.

Figure 3 illustrates the process to authorize discharge limits following the steps described above. The elements in the process are described in the following sections.

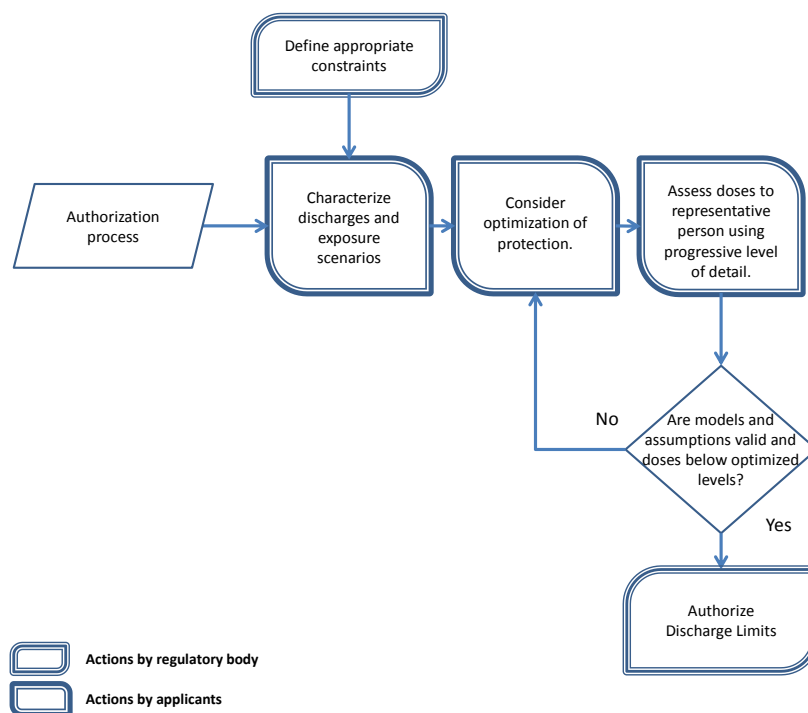


FIG. 3. Steps to authorize radioactive discharge limit, indicating those responsible.

¹³ The use of ‘best available techniques’ is discussed below and is considered in the Annex as an alternative way of applying optimization.

5.18. The level of detail required for the assessment to be submitted to the regulatory body varies considerably according to the facility and activity being considered. The regulatory body should provide guidance on this level of detail, including the format and content of the documents to be submitted. This guidance may be generic for different types of installations or provided on a case-by-case basis. Ref. [8] discusses the factor to be considered when deciding the level of complexity of the assessment of the protection of the public for facilities and activities.

5.19. The process illustrated in Figure 3 identifies actions by the regulatory body and by the applicants. It is important to remark that, when setting the authorized discharge limits for a facility or activity there should be a strong interaction to discuss the validity and assumptions used to estimate doses, the optimization process and the implications on the plant operational conditions which could be influenced by the discharge limits and conditions; for example, the liquid and gaseous waste fluxes and storage and the associated doses to the workers. This should be conducted in an iterative manner in order to reach an agreeable optimum solution from the overall radiation protection point of view.

ESTABLISHING A DOSE CONSTRAINT FOR APPLICATION TO THE CONTROL OF DISCHARGES

5.20. The government or regulatory body is responsible for establishing the dose constraint 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 for all sources under control remains within the dose limit. In specifying the dose constraint, local, regional and global sources may be considered.

5.21. The dose constraint for public exposure resulting from radioactive discharges to the environment should be a source related value with account taken of the doses from planned operations of all sources under control. It should be specified to serve as a boundary in specifying the range of options in optimization of protection and safety.

5.22. The dose constraint should be expressed in terms of annual effective dose and should be below the limit set for the effective dose of 1 mSv per year, and higher than the level of dose which could be considered for exemption. Therefore, dose constraints are likely to fall within the range of ~0.1–1 mSv per year [7].

5.23. The regulatory body should specify the dose constraint taking into account the expected typical public exposure conditions related to the practice under consideration, for

example, possible contributions from other sources at the local and regional level, present and in the future.

5.24. Dose constraints should be used prospectively and should not be regarded as limits to be applied during facility operation.

5.25. When setting the dose constraint, the government or the regulatory body should take into account:

(a) The characteristics of the location that are of relevance for the level of public exposure, for example the exposure pathways, the habit data and the occupation factors.

(b) The possibility or not of dose contributions from other authorized or foreseeable future facilities and activities. For example, in the case of a nuclear power plants, other existing or projected nuclear power plants to be built on the same site; in the case of hospitals in urban areas, more sources of radiation can be expected from other practices in the same city (for example, industrial applications and other medical applications) and; in the case of practices in isolated or remote areas (like uranium mining and milling), the assumption of contribution from additional local sources of radiation may be discarded.

5.26. Dose constraints should be set at levels that depend on the specific facility or activity and the expected exposure conditions at its location. However, national authorities may choose to develop generic dose constraints, for facilities activities of a similar design or characteristics (for example, for nuclear facilities, for uranium mining and milling activities or facilities, for 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—including the alternatives to optimization, like the use of the concept of best available techniques—is discussed in Section 5 and the Annex.

CHARACTERIZATION OF DISCHARGES AND EXPOSURE SCENARIOS

5.27. Preoperational research should be made to identify the inventories of radionuclides which would result in releases during operation of a facility or conduct of the activity, the possible discharge routes, the amounts that will be discharged to the environment and the radiation exposure pathways, and other relevant data parameters that could be used to estimate doses to members of the public. This could be based on analysis specific for the practice under consideration or based on the experience in similar practices.

5.28. The need for a detailed characterization of the discharges should depend on the projected magnitude of the dose to the members of the public in accordance with a graded approach. For small installations 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, where appropriate, from a consideration of the design, proposed operating characteristics and efficiency of the techniques used to minimize the discharge. Information from similar installations already in operation elsewhere should also be used (see, for example, Ref. [19]).

5.29. The relative importance of different exposure pathways will be dependent upon the nature of the discharge, the route of discharge and the physical and chemical characteristics of the radionuclides. In the case of discharges to the atmosphere, consideration should be given to the meteorological data at or close to the proposed site and possible deposition of radioactive material on land and subsequent transfer to crops and animals, as well as on standing water bodies and subsequent uses of water..

5.30. In the case of discharges to the aqueous environment, consideration should be given to the uses of water, such as for consumption, fishing, irrigation and recreation.

5.31. Preoperational studies should also be carried out to determine the existing levels of radiation in the area surrounding the facility prior to operation and should involve the determination of the external radiation levels as well as the concentrations of radionuclides in the environment (for example, water, soil, plants, crops, food). These studies should establish a baseline above which the impact of the discharge after it commences can be determined. This baseline can vary from site to site because of variations in natural background radiation and, in some cases, because of residual contamination from past practices, accidents or global fallout after nuclear weapon tests. The establishment of a baseline is particularly important with practices that discharge naturally occurring radionuclides (see Section 8 below). Detailed guidance on undertaking preoperational surveys is given in Refs. [10] and [20].

5.32. The characterization of the radiation exposure pathways should take account whether discharges are to the air or water, and in the case of liquid discharges, whether the discharge will be to a marine, estuarine or freshwater environment. For hospitals and small research laboratories, there may also be discharges of radionuclides to the sewerage systems.

5.33. When 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, the environment in these areas. This is particularly important when the representative person may live in a neighbouring country, for example, in the case where the facility is to be constructed at national border or on an international waterway.

CONSIDERATION OF OPTIMIZATION OF PROTECTION

5.34. Optimization of protection is the key process in setting discharge authorizations and it involves a number of different aspects. In relation to a discharging facility which may cause public exposure, the optimization should be a key part of the design and planning process and should also be kept under review throughout the whole lifetime of a facility. Optimization of the discharges forms part of the optimization of protection for the practice as a whole.

5.35. Optimization of 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. Aspects of the risks of accidental releases should also be considered as well as the impact of decisions on waste management on occupational exposures of the workforce. For example, reducing discharges may lead to an increase in radioactive waste stored on a site with a related increased risk of accidental releases and increases in occupational exposures, so that this may not be the optimum solution.

5.36. Optimization should involve examining the available options for reducing the discharge and all aspects of the impact of these options. Much can be achieved at the early stages of siting and design, account being taken of good practices elsewhere and the dose constraints established or approved by the government or regulatory body. In the case of liquid and gaseous residues that might be generated during operation, consideration should be given to keeping the residues to a minimum and further effluent treatment.

5.37. The main types of the effluent treatment are to provide either storage facilities for gaseous and liquid residues, so that, for example, short-lived radionuclides can decay before release to the environment, or abatement treatment that removes radionuclides from the effluent stream. Within these two broad categories, there may be a number of different options available. The various options should be identified and their features examined as far as possible.

5.38. Optimization should be conducted within some set of boundaries on the range of available protection options, e.g. the dose constraints discussed in previous paragraphs 5.20 to 5.26. An iterative analysis of each selected option should be performed. Further information on practical aspects of the optimization process and dose constraints is presented in the Annex.

5.39. There will be generally a number of complex trade-offs between various features which should be considered during the optimization process. These should include the following:

- (a) Trade-off between doses from discharges and future doses associated with the disposal of solid waste, if the decision was made to solidify the residues;
- (b) Trade-off between public exposures and occupational exposures (e.g. the reduction in public exposure at the expense of an increase in occupational exposure due to an improved effluent treatment system);
- (c) Choice between options whose characteristics are known with different degrees of certainty.

5.40. Whatever approach is used in determining the optimum option, it should be recognized that judgements are required about 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, for instance those responsible for nuclear safety, workers protection, public and environmental protection.

5.41. When the projected doses to the members of the public are in the order or below the exemption criteria, e.g., in the order of 10 μ Sv per year, a process for optimization should not be required on the basis that the efforts for further dose reduction would generally not fulfil the optimization requirements.

Optimization of protection and regulatory control of special radionuclides for particular practices

5.42. While the requirements for optimization of protection and the regulatory control must be applied similarly to all type of facilities and activities and radionuclides, certain radionuclides resulting from some practices have characteristics that require special consideration. Amongst these characteristics are the difficulties in managing some radionuclides during the full practice (for example when using unsealed sources in nuclear

medicine, which are administered to patients as part of a medical treatment) or the large volumes in the gaseous or liquid operational effluents involving with very low levels of activity concentration (for example, radionuclides resulting from neutron activation which may arise in the coolant system of nuclear power plants).

5.43. For these particular practices the discharges of some specific radionuclides may require a 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 of the public. This consideration may also result in the need of an adapted approach for the regulatory control of these discharges. Examples of these radionuclides are tritium and C-14 discharged from nuclear facilities, including nuclear power plants, and radionuclides (e.g. Tc-99m, I-131) used in hospital for medical diagnosis and therapy.

5.44. 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:

- (a) the technical characteristic related to the control of discharges of this 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) the economic characteristics, such as the costs of the abatement techniques which might be excessive and unjustified in the framework of the general optimization for the type of practice;
- (c) societal considerations such as public acceptance for the type of practice under consideration as well as individual and societal benefits from the class of facility or activity;
- (d) environmental and efficiency considerations such as the effects of releases of hazardous chemical substances or high energy consumption entailed by the radionuclides abatement techniques;
- (e) safety considerations such as those related to the safe storage of large amount of radioactive solid, liquid or gaseous material for long times, implying an increase in the risk of accidental releases;
- (f) radioactive waste issues, such as those related to the transport and storage of large quantity of waste containing low concentrations of intermediate- to long-lived nuclides;

(g) radiation protection considerations such as individual and collective doses received by workers in connection with the abatement process and the storage.

5.45. The regulatory body and the operating organization should take into account that, for the above mentioned practices and radionuclides, the optimal management option might not result in the minimization of the activity to be discharged, but in the application of more stringent verification of compliance measures, by the operating organization and the regulatory body, as relevant. This optimal management option and the justifications should be presented by the operating organization and endorsed by the regulatory body. Examples of the more stringent verification of compliance measures for complex installations, including nuclear facilities, could be (a) a radionuclide specific source and environment monitoring programme; (b) more detailed dose assessment to the representative person, including the identification of relevant exposure pathways; and (c) more frequent reporting to the regulatory body.

Decision aiding techniques

5.46. 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. It was mentioned before that when 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 should generally not be necessary. Nevertheless, the regulatory body should determine the type of installation that, despite the doses to the public due to releases during normal operation are very low, would require that an optimization process is conducted (for instance, this is the case for nuclear facilities or other complex installations).

5.47. Various analytical techniques have been proposed to assist in determining the optimized level of protection, which may be applied for discharges. 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 may 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 accident potential 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

5.48. In optimizing the protection of the public, the measures used in the management of wastes and discharges and the way they are applied should be considered and compared against other possible options. Concepts such as best available techniques¹⁴ are used in some States [21] and under certain international frameworks [22, 23] and in other industries for controlling pollutants generally; an adequate use of best available techniques corresponds to optimization and demonstration of best available techniques would demonstrate optimization. The best available techniques assessment does not simply consider what techniques are or could be available to reduce discharges but consider the situation as a whole to determine what is optimum, including the availability of the options and the costs involved.

Use of collective dose

5.49. The estimation of collective doses resulting from different options or alternatives (for example, different waste management and discharge options) and their direct comparison is another parameter which could be included in the optimization process.

5.50. Collective dose is a measure of radiation exposure from a source in a given group of population and can be obtained by multiplying the average dose to the exposed group by the number of individuals in the group [16, 24]. When estimating collective doses 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 [16].

5.51. There have been different uses of collective dose 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 compare this with the cost of the option to reduce discharges. This Safety Guide does not provide guidance on the use of collective dose; however, with the adequate considerations and care, collective dose could be a practical means to apply optimization. It is important to remark that collective dose is not to be used to attribute specific risk of health effects. Publication [16] discusses optimization and use of collective dose in more detail.

¹⁴ The term ‘best available techniques’ (BAT) in relation to particular processes, facilities or methods of operation to reduce wastes and the discharges of radionuclides to the environment, is discussed in more details in the Annex in the framework of the optimization of protection.

ASSESSMENTS OF DOSES TO REPRESENTATIVE PERSON

5.52. The establishment of an authorization of discharges should take into account the results of a previous assessment of the radiological environmental impacts commensurate with the radiation risk associated with the facility or activity [2]. Ref. [8] presents guidance on radiological impact assessment which should be used as the initial basis in the process of setting discharge limits. To set the discharge limits, prospective estimations of the dose to the representative person should be used to then back-calculate the acceptable optimized discharge levels fulfilling the established radiological criteria.

5.53. 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 required and the resources that should be allocated to it consistent with a graded approach. These matters should be discussed with and should be subject to the agreement of the regulatory body.

5.54. The level of details required of the assessment model should depend upon the type of facility under consideration, the nature of the discharge and the availability of information and be consistent with a graded approach. In order to make an effective use of assessment resources, a structured iterative approach should be used for assessing doses to the representative person. 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 data, as necessary.

5.55. At the time of setting the discharge limits, a site-specific assessment should normally be used for nuclear fuel cycle facilities and other complex installations

5.56. The use of generic assessments should be used for assessing the impacts from small facilities such as hospitals with small nuclear medicine departments and small research laboratories because discharges from such facilities are usually low to very low.

5.57. A generic approach may also be used to estimate doses to the representative person at the early stages in the lifetime of a complex installation (see Figure 2), for instance during the initial discussions about control of discharges or to set provisional discharge limits. This should be followed by a more site-specific realistic assessment; once more information became available during the licensing process. Ref. [8] provides guidance on the levels of details and the type of information needed to make 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.

5.58. When doses estimated with a generic approach are above the constraint, the reduction of projected discharges (the total amount of certain radionuclides) or their characteristics (for example, the points of discharge or the speed of the effluents to provide more dispersive conditions) by means of a technological improvement in the installation should be considered. Alternatively, a more detailed assessment (site specific or with more realistic models) should be applied. 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 to the public could lead to decisions which would result in lower doses to the public but with higher costs and possibly higher doses to workers, not resulting optimal.

5.59. The estimation of the effective dose which may be received by members of the public depends upon a number of factors, such as the behaviour of radionuclides in the environment and their transfer to people, the duration of exposure and other relevant factors. These factors cause a wide variation in the effective dose among the exposed population. However, for the purpose of setting discharge limits a conceptual individual receiving a dose that is representative of the doses to the more highly exposed individuals in the population (e.g. the representative person) should be used. The dose to the representative person is the equivalent of, and replaces, the mean dose in the 'critical group' [2].

5.60. The estimated effective doses for the representative person should be based on the reference person model [14, 24]. However, the habits (e.g. consumption of foodstuffs, inside or outside occupation factors, usage of local resources) adopted to characterize the representative person should be typical habits or characteristics of a small number of individuals representative of those most highly exposed. The highest habit data of certain exposure pathways (e.g. 95% percentile), for instance, consumption of milk and crops, should be used to characterize the representative person. However not all the extreme habits should be used to represent a single member of the population to avoid over estimation. Extreme or unusual habits should not dictate the characteristics of the representative persons considered [16].

5.61. In assessing doses to the representative person 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.

Internal exposure of members of the public may occur by inhalation of airborne radioactive material and by ingestion of the radioactive material that may become incorporated into foodstuffs and drinking water. External exposure may be caused by radioactive material in the air and deposited on the ground. More details on the exposure pathways relevant for assessment of doses to the representative person are discussed in Refs. [8, 12, 13].

5.62. Given that the initial authorization of a discharge from a facility has inevitably to be based on a prospective assessment, environmental modelling should be used. Dispersion models should be used to assess the activity concentrations in the air or water as a function of time and distance from the source of the discharge. Environmental transfer models and parameters should then be used to assess the activity concentrations in other environmental media relevant for doses estimation (e.g. sediment or food products). Dispersion and transfer parameters are given in Refs. [12] and [13]. The possible accumulation of long-lived radionuclides (with physical half-lives longer than one year) in environmental media (e.g. soil and sediments) should be taken into account.

5.63. Models for the assessment of the dispersion and transfers into the environment should be appropriate for the situation in which they are being applied, ensuring that the assessment methodologies provide reasonable accuracy. Where possible, the results of the selected models should have been supported through comparison of their results with data for similar exposure scenarios or, at least, by means of benchmarking procedures against other appropriate models. Different methodologies, including calculation tools and input data, can be used to carry out an assessment [12, 13]. The national regulatory body should be satisfied that the methodology adopted is adequate for the purposes of national practice and should decide — possibly in discussion with the proposers of the facility or activity which methodology is best suited to carry out a particular assessment.

5.64. Different age groups should be considered when determining the representative person. It is generally sufficient to consider exposures to three age groups (1 and 10 year old children and adults) while the embryo or fetus and breast fed infants also being considered in some limited circumstances [16], for example when, due to the radionuclides to be discharged, the exposure conditions to those could be foresee as more significant (e.g. radioiodine).

5.65. Further information on the representative person and the considerations for the assessments approach and modelling, including the level of detail, are discussed in [8] and [16].

5.66. When determining the location and lifestyle habits of the representative person it should be ensured that adequate protection is provided not only for local populations but also for populations remote from facilities now and in the future. Taking into account the lifetime of a discharging facility, the location and lifestyle habits of the representative person should be specified with regard to the present and future environmental conditions, land use, spatial distribution of population, food production, distribution and consumption plus other relevant factors.

AUTHORIZATION OF DISCHARGE AND CONDITIONS

5.67. The authorization of a discharge implies written permission from the regulatory body. The regulatory body may grant or question the application for an authorization of discharges on a justified basis or may impose additional conditions or operational limitations it deems appropriate for the purposes of protection and safety.

5.68. The regulatory body should record formally the basis for its decision on the authorization of a discharge, or on its amendment, renewal, suspension or revocation, and should inform the applicant, in a timely manner, of its decision, and provide the applicant with reasons and a justification for the decision.

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

5.70. Large complex facilities such as nuclear facilities are subject to a comprehensive licensing process which should include provisions for establishing detailed conditions for authorization of discharges. The conditions associated with authorization of discharges for simpler facilities, such as hospitals with small nuclear medicine departments, industrial applications or small laboratories, should be less onerous. These conditions 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) rather than doses to the public, which can only be estimated. The use of dose versus activity is more discussed in the Annex.

5.71. Discharge limits will be written and attached or incorporated into the authorization of the facility or activity, and will become the regulatory limits with which the operating organization or licensee should comply.

5.72. The period of validity of the discharge limits should be specified in the discharge authorization or elsewhere, with provision to review at intervals as deemed appropriate by the regulatory body. The period of validity for complex installations—like nuclear power plants, reprocessing facilities and radioisotopes production facilities—should be the same than the period of validity of the authorization of the practice, with provisions for its review, at least once every five years. More simple installations like facilities or activities using limited amounts of radioisotopes should be reviewed periodically but at longer intervals. A new source for which experience is limited should be reviewed by the regulatory body at least once in the first three years.

5.73. At any event, a review of the authorization for discharges should be conducted whenever modification of the plant or of its operational conditions is expected to affect significantly the characteristics or regime of radioactive discharges.

5.74. The operational limits and conditions in a discharge authorization should include, as appropriate, some or all of the following components:

(a) Restrictions relating to different operational states of the facility (e.g. separate authorized limits for maintenance and normal operation), different seasonal and environmental dispersion conditions (e.g. a restriction may be specified for facilities discharging into a river when the river level is low because of very dry weather, or when the river is prone to flood in very wet weather¹⁵);

(b) Limits on the activities of radionuclides or groups of radionuclides that can be discharged in a given time period (e.g. monthly, quarterly, annually) and on activity concentrations¹⁶;

¹⁵ Similarly, in the case of discharges into a tidal marine environment, the regulatory body may specify the period of the tidal cycle when the discharge should take place to ensure maximum dispersion.

¹⁶ A surrogate operational parameter may sometimes be used instead. For example, the discharge authorization of a facility in which xenon-133 is used in operations in fixed quantities could define the maximum number of studies that may be conducted in a given period of time. This approach has the merit of simplicity but is generally available only for relatively simple operations.

- (c) Source and environmental monitoring programmes and systems and the frequency of reporting of results to the regulatory body (the regulatory body should specify the form and required content of the reports);
- (d) Maintenance of the appropriate records (see para. 3.135 of GSR Part 3 [2]);
- (e) Reporting of proposed modifications to the regulatory body and any revisions to the radiological environmental impact assessment;
- (f) Actions to be taken in the event of exceeding of authorized limits or breaching of operational conditions;
- (g) Period of the operating license for the facility.

5.75. 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 must allow for what would be anticipated under normal operating events, for example, 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 [25]. The need for operational flexibility should be considered as part of the optimization process in setting the discharge limits.

5.76. 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 as an indicator of plant performance.

5.77. In addition to the discharge limits for certain groups of radionuclides, discharge limits should be specified for particular radionuclides. These radionuclides should be identified on the basis of their special significance, for instance due to the radiological importance or other aspects like the involvement of large volumes of liquid or gaseous wastes with very low levels of activity concentrations. Examples of these radionuclides are C-137, Co-60, C-14 and tritium (C-14 and tritium is discussed in a separate section above, para 5.42 to 5.45). In some cases the regulatory body may also impose limits on specific radionuclides that provide early indications of important changes in the operational status of the facility.

5.78. Discharge limits for groups of radionuclides rather than 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 should be applied for certain radionuclides that cannot be promptly analysed as part of routinely measurements at nuclear facilities (for example, Ni-63, Fe-55 and Sr-90). Airborne discharges from nuclear facilities are often grouped as follows: noble gases, halogens or iodine isotopes, and particulates. This grouping reflects different ways of sampling and quantifying the discharges and also dosimetric considerations: noble gases result in external exposure to the whole body; iodine isotopes result in thyroid doses; and particulates usually present a potential hazard of inhalation or ingestion to all of the organs and tissues of the body.

5.79. 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.

5.80. The regulatory body should include in the authorization conditions for reporting, for example:

(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.

5.81. The operating organization should take 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 discharge authorization issued by the regulatory body.

5.82. The operating organization should make available on request, as appropriate, results from source monitoring. This request may be incorporated within the conditions of the authorization or specified in other regulatory documents. The Annex provides further information on the possible forms of a discharge authorization.

DEMONSTRATION OF COMPLIANCE

5.83. In order to demonstrate that discharges are in compliance with the limits and in order to check the assumptions used to evaluate representative person doses, source and environmental monitoring programmes should be established [10]. For complex installations like nuclear power plants or reprocessing facilities, environmental monitoring should also provide an additional means, besides effluent monitoring, of checking for unexpected releases.

5.84. Simpler installations, like small hospitals or small research laboratories using short living radionuclides, may not need a permanent environmental monitoring programme [10]. However, a single monitoring campaign, close to the installation prior to and at the beginning of operations may be considered by the regulatory body as a requisite to verify compliance.

5.85. The requirements for on-site (source) and of-site (environmental) monitoring should be specified in the discharge authorization by the regulatory body.

Monitoring by the operating organization

5.86. Registrants and licensees should establish and use 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. The monitoring programmes developed by operating organizations should be approved by the regulatory body. Ref. [10] provides guidance for the source and environmental monitoring applicable to control of discharges.

5.87. Two general types of monitoring are appropriate in the context of control of discharges and the related public radiation exposure:

- (a) monitoring of the source, which implies measuring activity concentration or dose rates at the discharge point or within the activity and facility; and
- (b) monitoring of the environment, which involves the measurement of radionuclide concentrations in environmental media (including foodstuffs and drinking water) and dose or dose rates due to sources in the environment.

5.88. The objectives of the monitoring programmes should be to verify compliance with authorized discharge limits, to provide information and data for dose assessment purposes and to assess the exposure, to check the conditions of operation and the adequacy of controls on discharges from the source and to provide a warning of unusual or unforeseen conditions, where appropriate [10].

5.89. Some subsidiary objectives, which should usually be fulfilled by a monitoring programme, are (a) to provide information for the public; (b) to maintain a continuing record of the impacts of an installation or a practice on environmental radionuclide levels; and (c) to check the predictions of environmental models so as to modify them as appropriate in order to reduce uncertainties in the dose assessment [10].

5.90. In accordance with these general and subsidiary objectives, the monitoring programmes should include radiation and radioactivity measurements and the collection of relevant supporting information, for instance actual meteorological data when this is considered necessary, according to the level of discharges.

5.91. Monitoring programmes should be in line with the 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, while such monitoring should normally be undertaken around a facility in the nuclear fuel cycle [8].

5.92. The operating organization should establish an appropriate quality assurance programme covering the control of the discharge and the monitoring programme. The programme should indicate what corrective actions should be taken in the event of deficiencies in control and monitoring being identified. It should cover both sample collection and measurement.

Independent monitoring by the regulatory body

5.93. The regulatory body should make provision for independent monitoring. The characteristics and the resources devoted to independent monitoring should be based on a graded approach. The expected dose to the representative person should be taken into account (for example, practices leading to doses of the order of 10 μ Sv in a year would not require independent monitoring). However, some practices like nuclear reactors should undergo independent monitoring in any case for purpose different than discharge limits compliance. Such monitoring may be undertaken by the regulatory body or by another organization on behalf of the regulatory body that is independent of the operating organization.

5.94. 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 dose 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

5.95. A further aspect 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 of the actual discharges and 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.

5.96. The results of environmental monitoring can also be an input into retrospective assessments. It should be recognized that, as the actual discharges will be lower than authorization limits and due to the cautious nature of prospective dose assessments, the doses to the representative person estimated retrospectively will, in nearly all cases, be lower than those used to set the discharge limits. Measurements may be less than limits of detection, may include contributions from other sources (such as other installations, past accidental releases or fallout from past nuclear weapons testing) or may not be representative due to the characteristics of the sampling techniques (reduced in time and space, when compared to source monitoring data).

Records and reporting

5.97. Records should be kept by the operating organization of the results of monitoring and verification of compliance [10]. The regulatory body should establish the characteristics and frequency of reporting those records.

5.98. Reports from the discharge monitoring programmes should include the main operational and discharge features in the period covered by the report and a conclusion on trends observed by comparison with previous results. They should demonstrate that the discharges are within the authorized limits established by the regulatory body.

5.99. Operating organizations should report promptly to the regulatory body any levels exceeding the operational limits and conditions relating to public exposure and any significant abnormal increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the authorized practice.

5.100. Comprehensive guidance on objectives and framework for source and environmental radiation monitoring for demonstration of compliance with conditions of discharge authorization is provided in [10]. Additional technical information on programmes and systems for source and environmental monitoring is available in Ref. [20].

INSPECTION AND ENFORCEMENT

5.101. The regulatory body should verify compliance with the regulatory requirements and the operational limits and conditions of the discharge authorization. This should involve, as appropriate, audit of the operating organization's records (including those giving the results of discharge and environmental monitoring), review the periodic reports giving the results of the radiological environmental impact assessments, inspections and review of the results of the independent monitoring programmes.

5.102. The regulatory body should establish a process for identifying and managing any identified non-compliance with the regulatory requirements.

5.103. Where 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.

5.104. The actions to be taken by the regulatory body in response to non-compliance should be graded according to the seriousness of the failure. It may range from a simple warning, imposition of fines through to suspension or withdrawal of the authorization.

5.105. While no-compliance of discharge limits may be considered a breach in the regulations, given that the discharge limits are set considering the dose constraint (and not the dose limit) within a process of optimization or, in some cases, considering the results of the application of BEST AVAILABLE TECHNIQUES, it should be taken into account that the doses resulting from the discharge limits represents a level of dose for planning and managing protection and safety. If as the result of the operation the releases approaches or exceeds the discharge limits (e.g. resulting doses are above the specific dose constraint but still below the

dose limits), this should result preferable in an investigation of the situation, and development of modifications in the practice or follow-up actions that may be necessary.

Amendment, renewal, suspension or revocation of an authorization

5.106. 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.

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

5.108. The approval of the regulatory body should be obtained before any changes that may 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 and revise it as necessary.

INVOLVEMENT OF INTERESTED PARTIES

5.109. In the context of this Safety Guide, interested parties may typically include individuals or organizations representing the members of the public, parties in other States, especially neighbouring States, the news media, the regulated industry and facilities, agencies or regulatory bodies whose responsibilities may cover nuclear energy, scientific bodies and environmental groups (see Refs. [2] and [3]).

5.110. Any exchange of information relating to control of discharges may form part of other decision making processes, for example in the context of the governmental decision process of a major undertaking such as a decision to construct a large nuclear facility, or as part of the (regulatory) authorization process for construction of such facilities¹⁷. Such exchange of information are likely to consider social aspects, for example, public concern over the risks associated with radiation exposures and consideration of the doses to the public that might result from the discharges during operation.

¹⁷ Ref. [8] discusses the information relevant for different interested parties, if the framework of governmental decision and (regulatory) authorization processes related to facilities and activities.

5.111. In some cases there may be specific requirements for information exchange with interested parties before the discharge authorization 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 radiological environmental impact assessment (as described in Ref. [8]) should be a focal point for the discussions.

5.112. As noted in para. 2.18 there is a requirement to exchange information with other States when a discharge could cause public exposure to these states; for example, when a nuclear facility will discharge into an international waterway, or when the representative person may be in a neighbouring country¹⁸.

6. CONSIDERATION OF NATURALLY OCURRING RADIONUCLIDES IN DIFFERENT INDUSTRIES

6.1. In general, for facilities and activities not exempted from (nuclear) regulatory control there is no distinction in the manner to control the discharges from natural or artificial radionuclides. This is for example the case in nuclear fuel reprocessing plants, uranium conversion and enrichment plants, nuclear installations, uranium and thorium mining and processing facilities. This implies the use of dose limits, dose assessment, dose constraints and optimization—or best available techniques as relevant—accordingly to the national practice, as discussed in Section 5, paragraph 5.48 in in the Annex.

6.2. Some non-nuclear industries may have releases containing naturally occurring radioactive material (NORM). In some States, some of these industries involving NORM are under national authorities different to the regulatory body and therefore, discharges have not been subject to regulatory control with respect to radioactive substances. Where necessary, the regulatory body should cooperate and coordinate with other national authorities with responsibilities for NORM to ensure that radiation protection is taken into account in the management of any effluents.

¹⁸ Information exchange and, in some cases, consultation with the public and other interested parties is a policy requirement for environmental decisions in some Member States, for example, for those parties to the Aarhus Convention [26].

6.3. Generators of NORM releases include onshore and offshore facilities for oil and gas extraction, surface and underground mineral mines, mills and processing facilities, and the production of rare earth metals, fertilizers, thorium, titanium and ceramics using zircon sands for uses different than nuclear. Discharges from the extraction processes used for heavy metals usually also involve natural radionuclides. Therefore, most of the radionuclides will be found in products, by-products and solid waste. For example, in the phosphate industry, fertilizers become naturally enriched with 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 enriched in residues.

6.4. Where within those industries, the activity concentration in the material of any radionuclide in the uranium or thorium decay chains is greater than 1 Bq/g or the activity concentration of ^{40}K is greater than 10 Bq/g the airborne or liquid releases should be controlled according to the requirements for discharges from planned exposure situations (e.g. considering a radiological environmental impact assessment, specifying dose constraints, assessing doses to representative person, applying optimization or BEST AVAILABLE TECHNIQUES as relevant, authorizing discharge limits and establishing monitoring programmes).

6.5. It should be considered that the exemption levels for NORM could be higher than the exemption level for the nuclear and radiological industry and, consequently, influencing the specification and use of dose constraints, if applicable.

6.6. Some important differences which should be taken into account when specifying the condition to establish discharge authorizations for NORM are:

(a) The discharges are not always from a point source and often occur from large surface areas of stored material. This means that the predetermination of source terms and dispersion in the environment may be quite difficult and uncertain. With existing facilities, surveys should therefore be conducted to determine the geometry (point versus area sources) of the release.

(b) Greater reliance may need to be placed on environmental monitoring in assessing doses to the representative person. However, in areas with a relatively high level of natural background radiation, any increment in environmental levels caused by the discharge may be masked by the natural variability of the background levels;

(c) Specific assessments should be carried out to identify samples to be included in the environmental monitoring programme so that any increment may be followed in time. However, environmental monitoring may also be necessary to reassure the local population. In some circumstances, it may be necessary to include the monitoring of radon and dust close to main source areas, such as venting stacks and waste piles.

(d) The hazard from the non-radioactive components of the discharge may be more significant than those from the radioactive components and in these cases will normally determine the controls to be exercised over the discharge;

(e) Doses from radon where large quantities of NORM are handled or stored, including waste piles, may need to be assessed;

(f) Radioactive dusts may be exhausted through ventilation systems or resuspended from waste piles;

(g) While liquid discharges from offshore oil and gas installations are unlikely to lead to significant human exposure, there may be an impact on the environment needing an assessment and, if necessary control. The cleaning on land of pipes containing radioactive residues with elevated levels of radium may result in liquid radioactive wastes which should be regulated;

(h) Seasonal variations in rainfall may affect the radiological impact of liquid discharges from the facility. For example, there may be lower dilutions of the discharges in the dry season. Furthermore, sedimentation in periods of low water flow may be followed by remobilization of deposited sediments during periods of high rainfall.

6.7. The discharge of radionuclides from NORM facilities is the result of a complex interaction of geological, climatic and technological factors. Discharge routes need to be considered that are not relevant for other facilities:

(a) The discharge of radon from open pits and ventilation shafts;

(b) Drainage of radionuclides and their seasonal variations from tailings and piles;

(c) The use of the water, e.g., for public supply or for irrigation purposes, may include seasonal aspects that will strongly influence the doses received by members of the public

(d) Non-uniform discharges due to seasonal influences may also affect sediment deposition in freshwater receptors. Sedimentation in periods of low flow may be followed by remobilization of deposited sediments during high rainfall rate periods.

7. CONTROL OF DISCHARGES DURING DECOMMISSIONING

7.1. The conduct of a decommissioning is a post-operational situation which should be considered a different practice subject to authorization requiring specific regulatory provisions [27]. In general, two main options should be considered:

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

7.2. It is typical for effluent discharges to vary through the different phases of decommissioning. For example, as decommissioning leads to a progressive removal of radioactive sources the radioactive discharges may be reduced.

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, during 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 (immediate dismantling or deferred dismantling), consideration should be given to the following:

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

(e) The need to revise the discharge authorization, including any conditions relating to the source and environmental monitoring programmes to take account of any differences identified. The monitoring programmes should be robust enough 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 facilities usually takes place progressively over several years and is usually divided into different phases. Discharges of effluents containing radionuclides typically vary through these phases and the regulatory control should be applied on a case by case basis. Protection and safety should be optimized at each step, with account being taken of the experience gained in the previous steps. Because unexpected difficulty may arise during each step, regulatory control of the discharges should follow the conditions in each step.

8. PREVIOUSLY UNREGULATED PRACTICES

8.1. The regulatory body may identify existing practices or sources that are already releasing radionuclides to the environment but not under an authorization as described in this Safety Guide or with less stringent regulations with respect to the control of public exposure. This may be the case with some NORM facilities, but there may be other facilities in a country that are operating prior to the development and full application of regulatory requirements.

8.2. The regulatory body should, firstly, establish whether the practice or source falls within the scope of regulatory control (i.e. is not excluded from the application of safety standards). If so, the regulatory body should determine whether the provisions for exemption can be applied (see Section 4, para. 4.1 to 4.5 in this Safety Guide).

8.3. If authorization of the discharge is required, similarly to a new practice, discharges should be adequately characterized, exposure pathways identified and, radiological environmental impact assessment carried out (e.g. as defined in [8]) and a process to define discharge limits should be conducted (as presented in Section 5 in this Safety Guide).

8.4. The applicability of any dose constraints to this previously unregulated source should be established. Dose constraints for new practices and sources, strictly, should not be used because they only apply prospectively. However, the regulatory body may choose to also establish dose constraints for future operations of existing practices.

8.5. The operating organization should be required to demonstrate that the dose to the representative person is below the effective dose limit of 1 mSv in a year. Furthermore, consideration should be given to whether protection and safety can be further optimized. The regulatory body should base the discharge authorization on the results of the assessment and optimization study.

8.6. Exceptionally, if the assessed annual dose is found to be greater than 1 mSv, the regulatory body should consider setting authorized limits 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 one year. During this period of averaging, investigations should be carried out to determine how the discharge can be reduced so that within a few years, the dose to the representative person can be shown to be below the annual limit of 1 mSv. The authorization should then be reviewed during this period and a revised authorization issued.

8.7. The limits on effective dose to the representative person should only be applied to future discharges from the facility. They should not take into account the total dose resulting from past operations of the facility. If appropriate, the contributions to the effective dose from past operations should be addressed within an intervention framework [2].

REFERENCES

- [1] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1. IAEA, Vienna, 2006.
- [2] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).
- [3] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection (2007 Edition). IAEA, Vienna (2007).
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Control of Radioactive Discharges to the Environment, IAEA Safety Standards Series No. WS-G-2.3, IAEA, Vienna (2000).
- [5] INTERNATIONAL ATOMIC ENERGY AGENCY, Licensing Process for Nuclear Installations, IAEA Safety Standards Series No. SSG-12, IAEA, Vienna (2010).
- [6] INTERNATIONAL ATOMIC ENERGY AGENCY. Operational Limits and Conditions and Operating Procedures for Nuclear Power Plants, IAEA Safety Standards Series No. NS-G-2.2, IAEA, Vienna (2000).
- [7] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection of the Public and Protection of the Environment, IAEA Safety Standards Series, Safety Guide DS432, in preparation, IAEA, Vienna.

- [8] INTERNATIONAL ATOMIC ENERGY AGENCY. A General Framework for Prospective Radiological Environmental Impact Assessment and Protection of the Public, IAEA Safety Standards Series, Safety Guide DS427, in preparation, IAEA, Vienna.
- [9] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection Aspects in the Design of Nuclear Power Plants, IAEA Safety Standards Series No. NS-G-1.13. IAEA, Vienna (2005).
- [10] INTERNATIONAL ATOMIC ENERGY AGENCY, Environmental and Source Monitoring for Purposes of Radiation Protection, IAEA Safety Standards Series No. RS-G-1.8, IAEA, Vienna (2005).
- [11] INTERNATIONAL ATOMIC ENERGY AGENCY Radiation Protection and Radioactive Waste Management in the Operation of Nuclear Power Plants, IAEA Safety Standards Series No. NS-G-2.7, IAEA, Vienna (2002).
- [12] INTERNATIONAL ATOMIC ENERGY AGENCY, Generic Models for Use in Assessing the Impact of Discharges of Radioactive Substances to the Environment, Safety Reports Series No. 19, IAEA, Vienna (2001).
- [13] INTERNATIONAL ATOMIC ENERGY AGENCY: Revised Safety Report Series No 19: Volume 1: Screening Assessment of Public Exposure; Volume 2: Generic Models for Use in Assessing the Impact of Radioactive Discharges; Volume 3: Assessing Doses to Flora and Fauna, and Environmental Impacts due to Radioactive Discharges from Facilities and Activities. IAEA Safety Report Series, Vienna (in preparation)
- [14] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection', ICRP Publication 103, Elsevier, Oxford and New York (2007).
- [15] INTERNATIONAL ATOMIC ENERGY AGENCY. Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1. IAEA, Vienna (2010). (under revision DS462).
- [16] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Assessing Dose of the Representative Person for the Purpose of Radiation Protection of the Public and the Optimisation of Radiological Protection: Broadening the Process, ICRP Publication 101, Elsevier, Oxford and New York (2006).

- [17] INTERNATIONAL ATOMIC ENERGY AGENCY. Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4, IAEA, Vienna (2009) (under revision DS462).
- [18] INTERNATIONAL ATOMIC ENERGY AGENCY, Licensing Process for Nuclear Installations, IAEA Safety Standards Series SSG-12, IAEA, Vienna (2010).
- [19] UNITED NATIONS, Sources and Effects of Ionizing Radiation (Report to the General Assembly), Scientific Committee on the Effects of Atomic Radiation, UNSCEAR 2008 Report to the General Assembly, with annexes. United Nations, New York (2008).
- [20] INTERNATIONAL ATOMIC ENERGY AGENCY, Programmes and Systems for Source and Environmental Radiation Monitoring, Safety Reports Series No. 64, IAEA, Vienna (2010).
- [21] ENVIRONMENT AGENCY (2010), UK Principles (see <https://www.gov.uk/government/policies>).
- [22] OSPAR COMMISSION, 1992 OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic, 22 September 1992.
- [23] EUROPEAN UNION. Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control (Codified version).”
- [24] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication 60, Pergamon Press, Oxford (1990).
- [25] INTERNATIONAL ATOMIC ENERGY AGENCY, Setting Authorized Limits for Radioactive Discharges: Practical Issues to Consider, IAEA TECDOC Series No. 1638, IAEA, Vienna (2010).
- [26] UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE, The Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, UNECE, Aarhus (1998).
- [27] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, General Safety Requirements Part 6, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014).

Annex

**PRACTICAL CONSIDERATIONS IN SETTING
DISCHARGE AUTHORIZATIONS**

I-1. This annex summarizes key practical aspects related to setting discharge limits within an authorization process.

SPECIFICATION AND USE OF CONSTRAINTS

I-2. Dose constraints are source-related values of individual dose used in determining the best protection option, in the process for setting discharge limits.

I-3. Dose constraints for public exposure in planned exposure situations are required to be set by the government or the regulatory body (para 3.120 of Ref. [I-1]). In some cases, the operating organization has to propose a dose constraint for a particular facility and activity, which needs to be discussed and agreed timely by the regulatory body. The dose constraint is intended to ensure that the sum of doses from planned operations for all sources under control remains within the dose limit and therefore has to be below the pertinent dose limit, namely 1 mSv for the effective dose. On the other hand, a dose constraint is likely to be higher than the level of dose which could be considered for exemption (e.g., higher than ‘of the order of 10 μ Sv in a year’, for example, 100 μ Sv in a year as suggested in Ref. [I-2]).

I-4. In order to establish a generic dose constraint the regulatory body may consider previous guidance by the IAEA that suggested 0.3 mSv committed in a year as an appropriate value, on the basis of maximum levels of individual exposures generally used for optimization in nuclear fuel cycle facilities in various countries [I-3]. ICRP has not explicitly recommended a dose constraint for the control of discharges to the environment, but has suggested a value of 0.3 mSv per year in relation to disposal of radioactive waste and prolonged exposures [I-4, I-5, I-6] and see Table 8 of [I-7].

I-5. As recommended in para. 5.24 in this Safety Guide, dose constraints should not be used as a dose limit. A dose constraint has to be treated as a guidance level to establish discharge limits and inform decisions during the optimization process. More specifically, exceeding a dose constraint and reporting it immediately is not to represent a regulatory infraction, as would be the case of the dose limit.

I-6. 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 sources, the location of the source,

dose contributions from other authorized practices and foreseeable future practices and the exposure conditions needs to be considered. Other factors, such as economic and social factors as well as the views of interested parties could also be taken into account. The dose constraint for a specific source could exceed the generic value set at national level.

I-7. A dose constraint is not the only tool used in optimization. For example the application of BEST AVAILABLE TECHNIQUES, taking into consideration the cost and advantages, could similarly aid in ensuring that doses to the public are kept as low as reasonably achievable.

I-8. When considering the contribution to the exposure of the public from other authorized sources, local and distant and existing and planned practices needs to be considered For example, for nuclear installations, other nuclear installations on the same site or discharging to the same water body (particularly rivers and small lakes) could be observed or assumed to contribute to the exposure of the representative person under consideration.

I-9. Considering that the constraint is not only to consider other existing or planned sources but should be used as a boundary condition to guide optimization (para. 5.21 in this Safety Guide), in the case of multiple activities and facilities on the same site it is not appropriate to apportion the generic dose constraints divided exactly by the number of facilities. Usually a specific dose constraint has to be assigned to each facility or activity taking into account the factors mentioned in this Annex and in Section 5, ensuring that, once the protection is optimized with respect to each source, the resulting combination of dose does not exceed the dose limit.

I-10. In the case of facilities or activities in an urban environment, e.g. hospitals or industrial applications, more than one source could be always assumed to contribute to the exposure of the representative person. On the other hand, for facilities or activities located in remote areas, e.g. a uranium mine in an extremely remote area, the contribution from other local sources could generally be discarded and, consequently, a higher specific dose constraint could be set.

I-11. In the case of a hospital discharging to the sewage, the a specific dose constraint value needs to be set to take account of the exposure conditions of the workers at the sewage system used to collect and process liquid discharges, which are normally identified to define the representative person.

I-12. As discussed in previous paragraphs and in Section 5, there are different aspects to be considered and options to specify discharge limits which can be deemed to optimize the level of protection of the public; these may include using best available techniques as discussed in combination or not with a dose constraint. States may adopt these different options subject to the national regulations, as far as it 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-13. A scheme illustrating the possible use of a generic and specific dose constraints to establish discharge limits is presented in Figures I-1 and I-2 below. The generic dose constraint is to be set within the dose limit and higher than the dose which corresponds to the exemption criteria. Figure I-1 illustrate that the specific dose constraint for a facility or activity could be higher or lower than the generic dose constraint, depending of different factors determining the exposure conditions at the location of the representative person, mainly the influence or not of other sources.

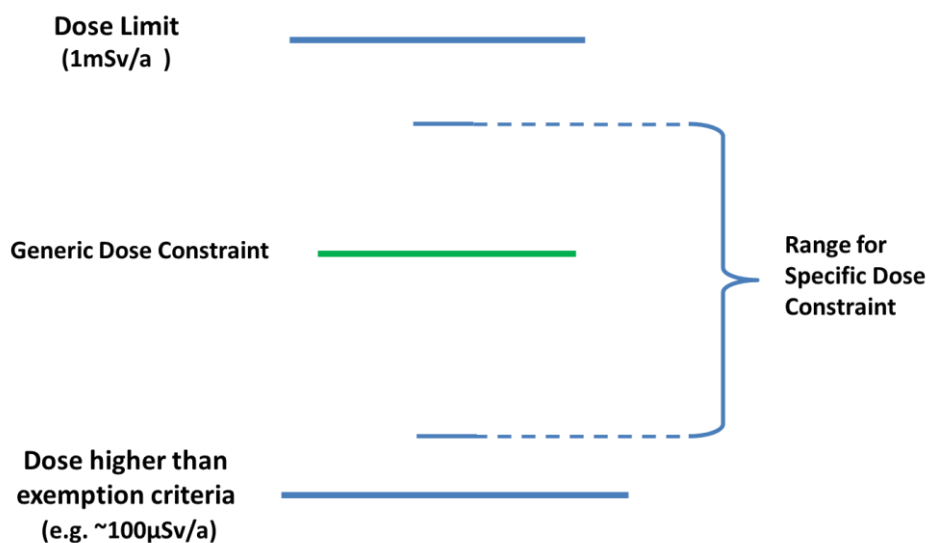


FIG. I-1. Relation between a generic and a specific dose constraints.

I-14. Figure I-2 illustrate that once the specific dose constraint is specified, the aim is to use it within the process of optimization to find the level of discharge which is optimal in terms of protection of the public. A margin for operational flexibility needs to be allowed considering the characteristic of the activity and facility and their operational features,

resulting in doses due to the authorized discharge limits slightly above the optimal releases and below the specific dose constraint. The margin for flexibility has to be justified.

I-15. Figure I-2 also indicates that the region below the specific dose constraint which counts for the optimization process could be used by some States to apply concept of best available techniques to find the optimal discharge limit. As mentioned in Section 5 in this Safety Guide when properly applied, best available techniques can be considered as a manifestation of the principle of optimization.

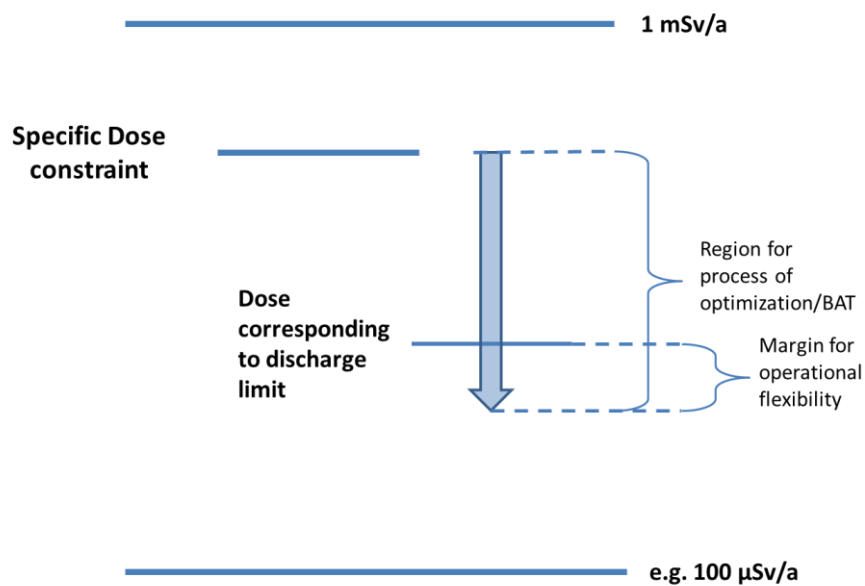


FIG. I-2. Dose to be used to set discharge limits.

I-16. Considering the technical characteristic of certain facilities and activities with respect to retention of radionuclides (for example good containment and filtering systems) and, particularly when best available techniques for the containment and abatement of radionuclides are used, it is possible that the estimated discharges result in doses below 100 μ Sv per year. In those cases, doses below 100 μ Sv per year can be used as the starting point to consider the specification of discharge limits including, when applicable, the optimization process (this is usually the case in most of the nuclear installations).

CHARACTERIZATION OF DISCHARGES

I-17. As outlined in para. 5.27 to 5.33 in the main text of this Safety Guide, once the need of an authorization was confirmed the applicant should characterize the nature of that discharge. For instance, this would be in terms of:

- Industrial process or activity and supporting assumptions;
- Radionuclide composition;
- Chemical and physical form of the radionuclides (related to behaviour in the environment);
- Routes of discharge and discharge points, including discharge characteristics such as stack height, exit velocity, exit temperature, maximum and average discharge rates;
- Total amount of various radionuclides expected to be discharged in one year; and
- Expected time pattern of discharge, including the need for and likelihood of enhanced short-term discharges.

I-18. For installations using small unsealed sources, such as hospitals and small research laboratories, discharges may be assessed on the basis of the estimated throughput, or the number of procedures, with allowance made for radioactive decay. For nuclear facilities, discharges may be estimated from a consideration of the design and actual previous or proposed operating characteristics.

I-19. For existing facilities, during a periodical safety review process, information will already exist that may be reviewed to support this process [I-8]. For new or previously unregulated facilities, it may be possible to make an assessment based on knowledge of similar facilities elsewhere. In either case, it is generally necessary to understand the way in which particular effluents are produced to assess the relationship between discharge and operational parameters, such as production figures, and the possible effect that waste treatment or abatement techniques may have on the amount discharged.

OPTIMIZATION

I-20. In practice, the extent to which formal optimization techniques are applied depends upon the operational status of the facility involved and the doses and risks that could potentially be involved. As discussed in Section 5 in this Safety Guide, many options may lead to an increased arising of solid radioactive waste and a corresponding trade-off between reduced public exposures and occupational exposures and risks. There could also be safety considerations such as an increased risk of accidental releases [I-9].

I-21. Different considerations will also be involved in optimization of new 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 to

construct the facility to reduce waste arising (including discharges) and thereby reduce occupational exposure and public exposure. However, during the operational stage, the options for reducing public exposures are more restricted than during design, due to the more limited possibilities of introducing changes in the processes or practices to reduce radioactive wastes and effluents. Optimization of public protection for on-going discharges is often undertaken considering the technical options available in an interactive way between the regulatory body and the operating organization [I-8].

I-22. Consideration of management options includes the evaluation of requirements for design and operational features, storage and treatment, and prevention of spills. For new facilities, protection can be optimized through the design, and construction for the operational, and decommissioning stages of the facility. Once a facility has been constructed and operation has begun, there are fewer options available to optimize. However, during operation there may be opportunities to review options for the management of discharges and re-authorization when major changes in operation are proposed. The management option may then consist of storage, treatment (abatement), redesign of the facility, or back-fit or upgrade of the existing facility or system design features. Possible abatement techniques and control methods are discussed elsewhere [I-8].

I-23. As discussed in Section 5 in this Safety Guide, decision aiding techniques should be employed to facilitate 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. The most common decision aiding techniques discussed in the literature are cost benefit analysis and multi-attribute analysis, although there can be others. The IAEA has already discussed decision-aiding techniques to some extent elsewhere [I-10] and further information is given in Ref. [I-8] in relation to the control of discharges.

I-24. There are a number of factors that will influence the decision on the optimized level of discharge. In particular, factors including public perception, political awareness, and potential consequences are relevant and likely to be different for discharges from nuclear facilities than from non-nuclear facilities such as hospitals. The effects on future generations, the ability to control the exposures and the amount of information available for making informed decisions may also be considered. The need to accommodate and balance the requirements of seemingly contradictory policies needs also to be considered (for example the requirements to minimize discharges – with associated requirements for waste treatment

measures that will increase the arising of solid waste – and the principle of waste minimization).

I-25. The factor that is of most importance will be dependent on site-specific attributes and also on the political and social pressures within a country. A list of such considerations is given in Ref. [I-8] and some points are also given here in the following paragraphs.

I-26. An important aspect that has to be taken into account is transboundary effects and the implications of regional and international conventions: e.g. conventions to prevent marine environment pollution like OSPAR, HELCOM and London (Waste Dumping) may involve additional requirements that have to be included as part of the optimization process. An example of this is the application of best available techniques, particularly in States in Europe by commitments related to the OSPAR convention [I-11]. Within this convention, Contracting Parties 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 land based installations discharges¹⁹.

BEST AVAILABLE TECHNIQUES

I-27. When properly specified, best available techniques²⁰ is effectively a different but consistent approach to optimization that focuses on techniques and technology rather than impact.

I-28. Within the context of IPPC²¹, best available techniques is explained as follows:

- ‘best’ in relation to techniques, means the most effective in achieving a high general level of protection of the environment as a whole;
- ‘available techniques’ meaning those techniques developed on a scale which 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;

¹⁹ See OSPAR PARCOM Recommendation 91/4 of 20 June, 1991 On Radioactive Discharges (1991). Available from: http://www.ospar.org/v_ospar/strategy.asp?v0=5&lang=1

²⁰ ICRP [I-9] recognized that for the control of radioactive emissions to the environment the principle of best available techniques not entailing excessive cost (BATNEEC) may be used, and that the principles of optimization and BATNEEC complement each other.

²¹ Integrated Pollution Prevention and Control (IPPC) Directive, EU, Brussels (1996).

- ‘techniques’ includes both the technology used and the way in which the installation is designed, built, managed, maintained, operated and decommissioned.

I-29. The European Commission has provided a series of reference documents on the application of best available techniques to specific industries which give information on relevant techniques, processes used, current emission levels, techniques to consider in determining best available techniques and emerging techniques (see Ref. [I-12]).

FORMS OF DISCHARGE AUTHORIZATION

I-30. There are a number of ways in which authorized discharge limits can be set based on limiting either dose, amount or concentration of radioactive material discharged from the facility. In most cases, the choice is a matter of preference on the part of the regulatory body, as well as the manner in which the regulatory body requires licensees to demonstrate compliance.

I-31. Some regulatory bodies prefer dose because it is viewed as a more fundamental quantitative limit and one that underlies the objective of the system of limitation of discharges. Setting limits in terms of quantities or concentrations of radionuclides to be discharged, on the other hand, is viewed by other regulatory bodies to reflect more closely the magnitude that is to be controlled and measured, and is therefore more closely connected to the actions that the registrant or licensee must take to control discharges.

I-32. Expressing limits in terms of a dose (i.e. in mSv per year) or an amount (or concentration) of radioactive material discharged (e.g. Bq per year or Bq/L) does not represent a fundamental difference, but rather one of preference. This is justified because a dose and an amount of radionuclides (or concentration of radionuclides) are directly proportional for any given site and representative person, and one can be converted to the other without difficulty. However, while an amount (or a concentration) of radioactive material is a directly measurable magnitude, dose to members of the public is always based on an assessment [I-8].

Radionuclide grouping

I-33. When discharge limits are specified in terms of quantity of radioactive material discharged, separate limits are usually specified for different radionuclides, or groups of radionuclides. Exceptions are cases in which the facility discharges only a few radionuclides, such as a hospital using only iodine or Tc-99m. However, even in situations where a mixture of radionuclides is discharged, it is unusual to set limits on each individual radionuclide,

because such a practice will usually be cumbersome and unnecessary, in which case one limit on total activity released may be used. Factors influencing the choice of radionuclide groups include: the feasibility of measuring one or more radionuclides within the group; indicators of plant performance; contribution to dose.

I-34. For larger facilities that may discharge a variety of radionuclides, limits are generally imposed on groups of nuclides that share similar characteristics, although limits may also be imposed on specific radionuclides that are deemed to be of special significance. For example, airborne discharges for nuclear plants are often grouped as follows: noble gases, halogens or iodine isotopes, and particulates. This grouping reflects dosimetric considerations: noble gases result in external exposure to the whole body, iodine isotopes result in thyroid doses, and particulates usually present a potential hazard of inhalation or ingestion to all of the organs and tissues of the body. They also reflect different ways of sampling and quantifying the discharges. The grouping may also be extended to include gross alpha and gross beta activities. Amongst radionuclides of special significance needing specific limits and consideration, tritium and C-14 should be considered (as discussed in Section 5 of this safety Guide).

I-35. Grouping of radionuclides is also useful in situations in which members of selected radionuclide groups arise together, and therefore the occurrence of one indicates the presence of the others in the group usually, although not always, in fairly fixed proportions. Such grouping has the merit of achieving simplicity in both the formulation of the limits as well as their implementation. The radionuclide of the group that is most easily detected at the desired sensitivity is often used in specifying the discharge limit for the group.

I-36. In some cases, a regulatory body may impose limits on specific radionuclides that provide early indications of changes in the operational status of the facility, or that may make an exceptionally high contribution to the total off-site dose. When limits are specified for groups of radionuclides, the practice is usually to set the limit for the group on the basis of the characteristics of the most radiotoxic radionuclide of the group.

Site or facility specific limits

I-37. Discharge limits, whether specified in terms of dose or quantity of radioactive material released, may be specified either for the whole site, for each unit within the site, or even for each discharge point, such as stack or pipe. A unit in this context means an identifiable entity that generates airborne or liquid wastes. 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 points 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 nearly all cases regulatory bodies impose an individual unit limit, but in some cases regulatory bodies impose only a site limit, with no limits on individual units [I-8].

Time interval for demonstrating compliance

I-38. The basic interval over which compliance is expected to be shown is almost always one year, usually a calendar year, although a rolling 12 month period is also used. The advantage of the latter is that it is believed to permit closer supervision of the facility by the regulatory body, but it is administratively more cumbersome to implement.

I-39. Although annual discharge limits are almost invariably used and are considered as the primary means of regulatory control, some regulatory bodies consider the need to establish shorter periods to demonstrate compliance. This is justified due to the concern that the validity of the assumptions used in setting annual discharge limits (e.g. in the estimation of doses to representative person) may not be applicable for short-term discharges. For these cases dose assessments needs to be done, for instance, on monthly or quarterly basis.

I-40. Parameters are typically chosen to be representative of annual averages. For example, the prevailing wind direction and speed, the degree of stability of the atmosphere, and the dietary habits applied are usually annual averages. In the absence of discharge authorizations for periods shorter than a year, it is at least theoretically possible that the facility may discharge a significant fraction of its annual allowance over a short duration, or a series of short durations, with significantly different radiological impact. For example, if a significant proportion of the discharge occurs during a period of exceptional atmospheric stability, the radioactive material would not be dispersed as much as the annual average calculations would indicate, thus leading to higher doses. Short-term limits are therefore often specified in addition to the annual limits. The short-term limits also allow the regulatory body to more closely monitor the facility's performance, and to take action as appropriate should 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].

Operational flexibility

I-41. Based on the optimized discharge levels and operational experience the regulatory body will set authorized discharge limits. Despite the dose under consideration are below dose

limits, exceeding discharge limits will normally initiate licensee and regulatory actions (e.g. investigation, corrective measures). There is therefore a need to allow for operational flexibility in setting discharge limits in order to avoid unnecessarily frequent violations of regulatory requirements that would result in significant and needless expenditure of resources, negative public perception, and frequent interference with the operation of the facility.

I-42. Authorized discharge limits are generally set higher than the optimized levels [I-8], although within the specified dose constraints, providing an allowance for operational flexibility. How much operational flexibility should be permitted is a matter of judgement on the part of the regulatory body, but at a minimum it must allow for what would be anticipated under normal operating events. These events include plant conditions that lead to a temporary increase in discharge levels of relatively short duration, usually hours to days, but are not classified as an incident or accident. For example, in the case of a nuclear medicine department, the event may be a number of patients seen that is significantly higher than average. For other types of operation, it may be a temporary failure or loss of efficiency of an effluent treatment system. Previous experience with the facility in question or other similar facilities can provide useful information on the minimum allowance for flexibility that needs to be permitted.

I-43. Some regulatory bodies set this at a level that is the minimum indicated by experience, or by past performance of this particular facility. Specific guidance cannot be provided to assist in this choice; it will be determined by the framework of national policy and commitments made through international agreements. The major point, however, is that sufficient allowance is made for operational flexibility to allow for normal operational variations for the type of facility under consideration [I-8].

Period of validity of the discharge authorization

I-44. While in principle the discharge authorization should have the same validity period than the authorization of the practice (para 5.72 in this Safety Guide), some regulatory bodies issue discharge authorizations that have a shorter period of validity, subject to a revision within the framework of a periodical safety review. In those cases, at the end of the period of validity, authorizations are reviewed, and updated, if necessary, based on current information related to public exposure. There is no standard period of validity; it may vary from two to three years up to five or more 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 bases on which the discharge

authorization was initially issued. Some regulatory bodies have the legal possibility to review and update the authorizations if necessary and do not apply a specified limit on the validity of the discharge authorization.

I-45. It is usual to require facilities and activities to obtain approval from the regulatory body before making any changes that may affect doses or the safety of operations. However, the accumulation of such changes over a period of time may produce a qualitative change in safety level that can only be detected through a complete review of the overall operation. The period of validity will also be 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 facility or activity review.

I-46. In other cases, the period of validity of the authorization may be equal the expected design 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, periodically reviewing 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 location and composition of the representative person and factors such as the locations of dairy farms, vegetable gardens, population centres, dietary habits, and other factors that enter into the calculation of the dose to the critical group and the collective dose for the site, have not altered or are taken into account. Any significant changes are generally required to be reported to the regulatory body, the doses are recalculated, and the authorized limits adjusted accordingly.

REFERENCES TO ANNEX

[I-1] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

- [I-2] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection of the Public and Protection of the Environment, IAEA Safety Standards Series, IAEA, Vienna. [DS432]
- [I-3] 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] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection Policy for the Disposal of Radioactive Waste, ICRP Publication 77, Pergamon (1997).
- [I-5] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiation protection recommendations as applied to the disposal of long-lived solid radioactive waste, ICRP Publication 81, Pergamon (1998).
- [I-6] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Protection of the Public in Situations of Prolonged Radiation Exposure, ICRP Publication 82, Pergamon (1999).
- [I-7] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection', ICRP Publication 103, Elsevier, Oxford and New York (2007).
- [I-8] INTERNATIONAL ATOMIC ENERGY AGENCY, Setting authorized limits for discharges: practical issues to consider. TECDOC 1638, IAEA, Vienna (2010).
- [I-9] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Assessing Dose of the Representative Person for the Purpose of Radiation Protection of the Public and Optimisation of Protection: Broadening the Process, ICRP Publication 101, Pergamon Press, Oxford and New York (2006).
- [I-10] INTERNATIONAL ATOMIC ENERGY AGENCY, Optimization of Radiation Protection in the Control of Occupational Exposure, Safety Reports Series No. 21, IAEA, Vienna (2002).
- [I-11] OSPAR COMMISSION FOR THE PROTECTION OF THE MARINE ENVIRONMENT OF THE NORTH-EAST ATLANTIC, 1992 OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic (1992). Available from: <http://www.ospar.org/eng/html/welcome.html>

[I-12] EUROPEAN COMMISSION, Best Available Techniques (BAT) reference documents <http://eippcb.jrc.ec.europa.eu/reference/>

CONTRIBUTORS TO DRAFTING AND REVIEW

Berkovskyy, V.	Ukrainian Radiation Protection Institute, Ukraine
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.	Consultant, Austria
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