DS442

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IAEA SAFETY STANDARDS

for protecting people and the environment

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Regulatory Control of Radioactive Discharges to the Environment

(DPP Tittle is *Regulatory Control of the Releases of Radioactive Material from Facilities and Activities*. The current tittle is proposed to make a strongest link to the Safety Guide which is being updated)

DRAFT SAFETY GUIDE

DS442

Revision of WS-G-2.3

IAEA

International Atomic Energy Agency

FOREWORD

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CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. Facilities and activities[1] [1] that use radioactive sources, including nuclear reactors, are designed, built, licensed, operated and maintained in a manner to prevent or minimize releases of radioactive materials to the environment. However, some facilities and activities may generate a variety of gaseous and liquid effluents during their normal operation, containing minor amounts of radioactive residues that, owing to the low activity concentrations and high volumes involved, would be, technically difficult to avoid or may have and an excessive and unjustified cost from the radiological protection perspective.

1.2. In accordance with radiation protection principles, safety fundamentals and objectives and the requirements established in the IAEA Safety Standards [1, 2], these effluents need to be managed in order to ensure the optimized protection of workers and the public, and protection of the environment, without imposing unnecessary burdens to the responsible organizations or individuals operating such facilities or conducting such activities.

1.3. In these cases it is appropriate to permit the release of these residues to the atmospheric and aquatic environments, establishing regulatory conditions for the management and the control of these effluents to be released.

1.4. The term 'discharge' is defined in [2] and is used to refer to the on-going or anticipated authorized releases of gaseous, aerosol or liquid radioactive material 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.

1.5. Accordingly to the IAEA Safety Standards [BSS], 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 control[2] of radioactive discharges.

[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.

[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.

1.6. Members of the public may be exposed to radiation as a result of such discharges to the environmental media.

1.7. This Safety Guide is concerned with the application of the Safety Requirements to the regulatory control of discharges established in the BSS [2] and takes account of the advice given in a number of relevant Safety Guides [3, 4, 5, 6, 7, 8] and with the experience from IAEA Member States.

1.8. This Safety Guide updates and thereby supersedes a Safety Guide issued in the year 2000 on regulatory control of discharges[3].

OBJECTIVE

1.9. The objective of this Safety Guide is to provide governments, regulatory bodies, applicants, registrants and licensees[4], as defined in the BSS, with a structured approach to limit the radiation exposures to the public resulting from discharges resulting from normal operations 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 and on demonstrating compliance with them and enforcing them.

1.10. This Safety Guide should be used by those applying for an authorization for discharges to the environment and those reviewing and authorizing them, as part of an authorization process, as described below. It may also be of relevance to other interested parties.

SCOPE

1.11. The scope of this Safety Guide is limited to discharges to the atmosphere of airborne (gases and aerosols) or discharges to surface waters of liquid effluents from activities and facilities during normal operations in planned exposure situations[5],. Disposal of solid radioactive waste, injection of liquids containing radioactive materials in underground water, and the releases to the environment arising from accidents are not addressed in this Safety Guide.

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

[4] The term ‘operator’ is defined in [11] and it is used throughout this Safety Guide to encompass applicants, registrants and licensees.

[5] A planned exposure situation is defined in [2]. Another word used as a synonymous in this Safety Guide is ‘practice‘[11].

1.12. This Safety Guide provides guidance on a procedure to establish the regulatory control of the discharges in connection with an authorization process. Wider aspects of the authorization process of activities and facilities are not considered. The authorization of discharges from new and modified facilities together with the review of established discharge authorizations are considered.

1.13. This Safety Guide addresses the derivation of authorized operational limits for discharge, the demonstration of compliance with the authorization and discusses the need for radiological monitoring programmes. An important input into the process of controlling discharges should be the prospective assessment of the level of protection of public and the environment against the effects of radiation. A separate Safety Guide considered the requirements for such impact assessments for both the public and the environment [6]. Only limited reference is made in this Safety Guide to the principles underlying such 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 assessment models and data.

1.14. The facilities and activities considered cover a wide range of radioactive sources from, for example, those used in the general industry, those used in medicine and research to nuclear reactors and reprocessing plants. It also covers the controllable discharges which may result during uranium mining and milling. Consideration is also given to the discharge of naturally occurring radioactive material (NORM).

STRUCTURE

1.15. Section 2 presents the basic requirements and concepts contained in the Safety Requirements relevant to the control of discharges including the general responsibilities of governments, the regulatory bodies, registrants/licensees and other relevant parties. Section 3 discusses the principles of radiation protection applicable to the control of discharges. Section 4 provides guidance and 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 characteristics of the discharges and the exposure scenarios used to define the discharge limits, the consideration of the optimization, the conditions in the authorization and the compliance. Section 6 covers the particularities of facilities with naturally occurring radioactive material. 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 which should be taken into account when setting the discharge authorizations.

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

2.1. This section presents the safety objectives, requirements and concepts contained in the IAEA Safety Standards relevant to the regulatory control of discharges and protection of the public and the environment.

GENERAL

2.2. The Fundamental Safety Principles [1] establishes, among others, principles for ensuring the protection of the public and the environment, now and in the future, from harmful effects of ionizing radiation.

2.3. The requirements for a governmental, legal and regulatory framework for safety are established in the General Safety Requirements [14] and it is assumed in this Safety Guide that these requirements have been fulfilled.

2.4. The BSS [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 operators) which are outlined below.

2.5. The consideration of the protection of people and the environment is included in the Safety Fundamentals [1] and the BSS [2]. The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation [1]. This safety objective has to be achieved without unduly limiting the operation of facilities and the conduct of activities [1]. The BSS defines 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, BSS 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].

2.6. 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 provides for appropriate protection of the environment against harmful effects of radiation [2].

2.7. 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 only (e.g the endpoints of the assessment to define discharge limits is dose to the representative person). This approach assumes that the environment is protected by mean of the conditions resulting in the authorization for the practice[6].

2.8. The following section contains extracts from the BSS [2] relating to planned exposure situations of relevance to the control of radioactive discharges.

JUSTIFICATION

2.9. Paragraphs 2.8 and 2.9 of the BSS3 [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".

2.10. Requirement 10 of the BSS [2] states: "the government or the regulatory body shall ensure that only justified practices are authorized".

OPTIMIZATION

2.11. Requirement 31 of the BSS [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.'

2.12. The BSS goes on to lay down 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'.

2.13. The BSS specifies 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) 'shall establish or approve constraints on dose and on risk to be used in the optimization of protection and safety for members of the public.' (paragraphs 3.119 and 3.120 in the BSS [2])

[6] Some States may consider more explicitly the protection of the environment, for instance including in the assessments the estimations of radiation exposures to flora and fauna. This may be considered necessary in some environmental circumstances needing special consideration (such as in protected areas or where there are endangered species). However, in general the protection of flora and fauna is not the limiting factor in setting discharge authorizations. Ref. [6] discusses protection of the environment, in the framework of radiological environmental impact assessment, with more detail.

2.14. Para. 3.22 of the BSS [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”.

2.15. Requirement 11 of the BSS [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”.

2.16. In applying the principle of optimization of protection and safety in relation to public exposure the BSS [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

2.17. Paragraph 3.132 in the BSS [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[7] 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.'

2.18. The BSS 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 potential radiological environmental impacts[8] undertaken in accordance with national requirements.

DOSE LIMITS

2.19. Requirement 12 of the BSS [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".

[7] In relation to the control of radioactive discharges the representative person can be considered to be the same as the previous 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.

[8] Guidance on radiological environmental impact assessment which should be used as an input to the establishment of discharge limits is provided in [6].

TRASNBOUNDARY IMPACTS

2.20. The BSS 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 of control of the State in which the source is located' (BSS 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.

PERIODICAL REVIEW

2.21. The BSS 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' (BSS paragraph 3.134 [2]).

2.22. Para. 3.132 of the BSS [2] requires registrants and licensees in applying , for and authorization for discharges, as appropriate" —i.e. consistent with a graded approach— ": (a) to "determine the characteristics and activity of the material to be discharged, and the possible points and methods of discharge" (b) to "determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public"; (c) to "assess the doses to the representative person due to the planned discharges" ; (d) to "consider the radiological environmental impacts in an integrated manner with features of the system of protection and safety, as required by the regulatory body; and (e) to : submit to the regulatory body the findings of (a) – (d) as an input to the establishment by the regulatory body […] of authorized limits on discharges and conditions for their implementation".

MONITORING

2.23. 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 BSS and para. 3.135 [2])[9]. 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 (operators) including the requirement 'to verify the adequacy of the assumptions made for the assessment of public exposure and radiological environmental impacts'.

2.24. Registrants and licensees are required by para. 3.137 of the BSS [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

2.25. The specific requirements relating to a graded approach are given in GSR Part 1, GSR Part 3 and GSR Part 4 [14], [2] and [15]. In relation to the control of discharges, the graded approach should be reflected in the application of the requirements of the BSS in planned exposure situations (Requirement 6 of Ref. [2]). The resources devoted to assess and control discharges and the scope and stringency of the regulations have to be commensurate with the magnitude of the radiation risk and their amenability to control.

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

3. PRINCIPLES OF PROTECTION TO CONTROL DISCHARGES

3.1. The principles of radiation protection that should be used to control radioactive releases to the environment from an activity or facility during planned exposures situations are those of justification, dose limitation and optimization. These principles are described in more details in [2] and [5].

JUSTIFICATION

3.2. 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.

3.3. 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.

DOSE LIMITATION

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

(a) An effective dose of 1 mSv in a year[10];

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

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

These dose limits represent the maximum dose that should be applied to control the radiological impact to public discharges when setting discharge limits.

OPTIMIZATION

3.5. 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 individual (workers and members of the public) subject to

[10] In special circumstances a higher value of effective dose in a single year could be permitted provided that the average effective dose over five consecutive years does not exceed 1 mSv per year.

exposure and likelihood of exposure being as low as reasonably achievable, economic and social factors being taken into account" [1], should be applied when setting discharge limits.

3.6. 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.

3.7. Further guidance on the optimization process relating to the control of discharges is given in Section 5 of this Safety Guide.

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 defined in [2], for example releases of natural 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 define when the discharges are excluded[12] 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. The components of the authorization process should be defined by the regulatory body and Figure 1 illustrates a scheme to decide whether a discharge authorization is required.

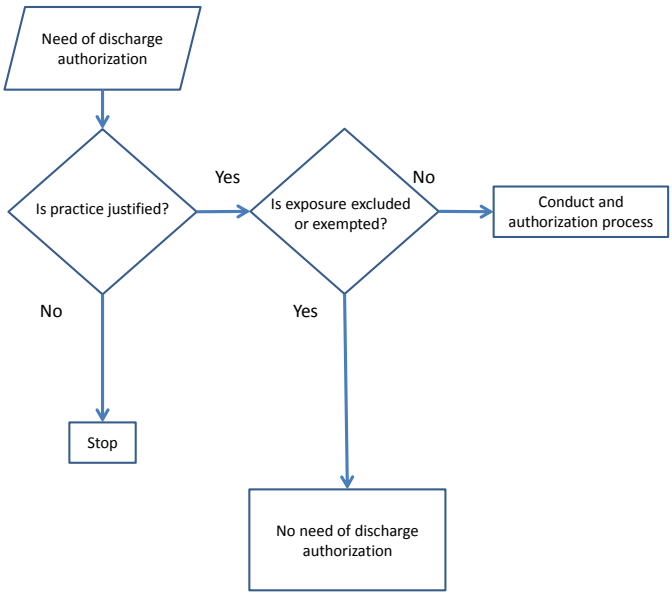

Figure 1: A decision process to determine the need of a discharge authorization.

[11] The criteria for exemption are specified in Schedule I of the BSS [2] and information is also provided on levels of activity and activity concentrations of a large number of radionuclides to assist with exemption. However, those values 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.

4.3. BSS [2] indicates that an effective dose of the order of 10 μSv in a year received under all reasonably foreseeable circumstances would imply no need of an authorization. This dose criterion should be applied to the representative person.

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. An ‘authorization process’ is a term defined in the BSS [2] and is a formal procedure established in the national regulatory framework by which a regulatory body or other governmental body grants written permission, at different stages of the life of a facility or the development of 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. For simple facilities or activities, like hospitals and small laboratories, the authorization process should normally consist of one stage.

5.4. For complex facilities, like nuclear power plants, 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, remediation of a site and release from regulatory control. Figure 2 describe schematically the stages in the lifetime of a complex facility and the timing when the control of discharges should be considered.

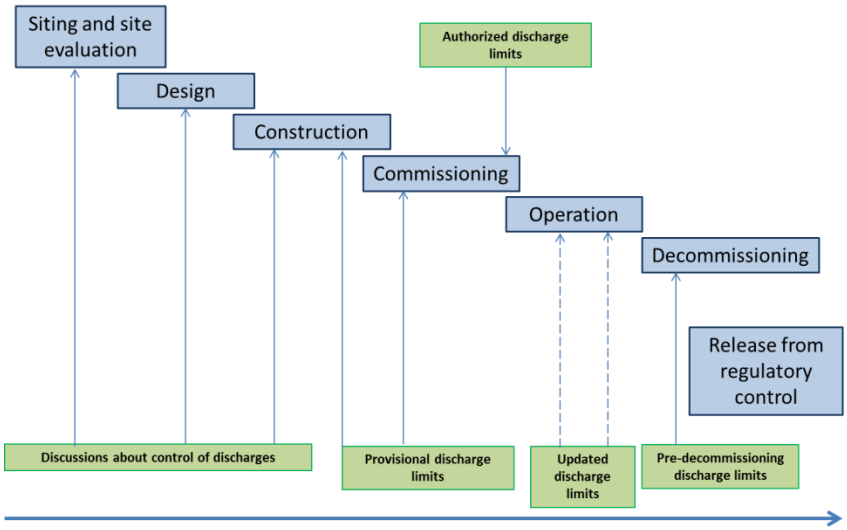

Figure. 2: Stages in the lifetime of a facility and the timing when the control of discharges should be considered.

5.5. 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 water bodies and its radiological impact on the public, generation of waste, and waste management and its impact to workers. [6] provides guidance for radiological environmental impact assessments for activities and facilities. This information should be sufficient to allow the regulatory body to form an opinion on the acceptability of the practice. In some circumstances a provisional discharge authorization could be issued before construction starts.

5.6. 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.

5.7. During the operation phase the discharge authorization should be reviewed, as part of the periodic safety review [2].

5.8. 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, modification of the representative person or changes in the environmental dispersion conditions.

5.9. 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 previous to the start of the decommissioning activities.

5.10. When an activity or facility is released from regulatory control after decommissioning, normally the radiological exposure scenario implies that a discharge authorization is no longer required, e.g. the releases to the environment after decommissioning are effectively zero. However some practices like mining or milling of uranium, after decommissioning could need a certain form of discharge authorization and the associated regulatory control. For these situations, the regulatory body should define this discharge authorization and the necessary monitoring programme on a case-by-case basis.

5.11. 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.

5.12. 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. For example, registration may be appropriate for a moderately-sized nuclear medicine department using radionuclides for diagnostic purposes.

5.13. 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

5.14. 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 that may discharge radionuclides into the environment. This includes simple facilities, for instance hospitals, and those more complex installations such as nuclear power plants. Additional explanation of the licensing process for nuclear installation may be found in Ref. [3].

5.15. 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.

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

(a) The regulatory body should establish an appropriate dose constraint or define the applicable dose constraint for the facility or activity under consideration.

(b) The applicant should characterize the discharges and the main exposure pathways identified, in order to assess the radiological environmental impact. Other relevant sources of planned exposures such as nearby sites that discharge radionuclides plus any direct external radiation sources from the site that can lead to exposures of the representative person should also be identified.

(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 factors.

(d) The applicant should assess the doses to the representative person (this may involve a graded approach starting with a simple cautious generic assessment and if required a more detailed site specific study).

(e) The applicant should submit the results of the assessment to the regulatory body. The regulatory body should evaluate 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 illustrate the process to authorize discharge limits following the steps described above.

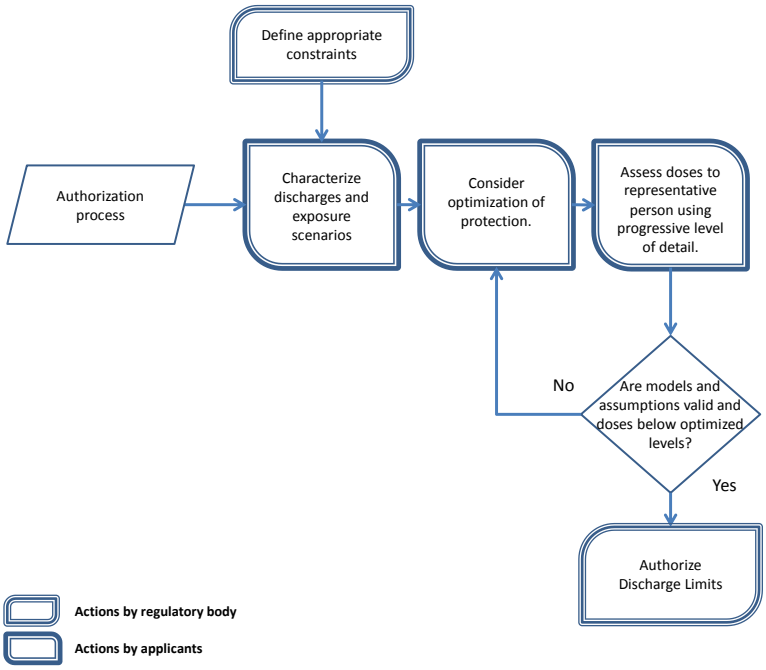

Figure 3: Steps to authorize radioactive discharge limit, indicating those responsible.

5.17. The level of detail required for the submission varies considerably according to the facility and activity being considered. The regulatory body should provide guidance on this, 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.

5.18. 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 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 to an optimum solution from the overall radiation protection point of view.

ESTABLISHING A DOSE CONSTRAINT FOR APPLICATION TO THE CONTROL OF DISCHARGES

5.19. The government or regulatory body should establish 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 defining the dose constraint, local, regional and global sources may be considered.

5.20. 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 defined to serve as a boundary in defining the range of options in optimization of protection and safety.

5.21. The dose constraint should be expressed in terms of annual effective dose and therefore should be set at some fraction of the effective dose limit of 1 mSv in a year. Like the dose limit, for public exposure, it relates to the dose to the representative person.

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

5.23. When setting the dose constraint for a particular source, the government or the regulatory body should take into account:

(a) The characteristics of the source and of the practice that are of relevance for public exposure, for example the amount and types of radionuclides, the physical properties and chemical forms and the discharge pathways.

(b) Good practice in the operation of similar sources; for example experience from well managed operations in other comparable installations should also be taken into account

(c) Dose contributions from other authorized practices or from possible future authorized practices; for example, account should be taken of doses from possible future sources and practices, for example, in the case of a nuclear reactor, other nuclear reactors to be possible built on the same site.

(d) The opinion of the applicant (operator), suitably justified from the operational and radiation protection point of views.

5.24. The final choice of the dose constraint should have regard for the need for flexibility in the process of optimizing protection for different competing exposure situations, for example, for the trade-offs between public exposure and occupational exposure.

5.25. The selection of the value for the dose constraint should consider the practicability of reducing or preventing the exposure, the expected benefits of the practice to individuals and society, other societal considerations relating to the practice; national or regional factors, together with a consideration of international guidance and good practice elsewhere.

5.26. The chosen dose constraint for discharges should relate to the total dose from both gaseous and liquid effluents. However, the representative person may be different for these two types of discharge. Thus, environmental modelling should be used to demonstrate that the total radiation dose to the more exposed of the representative persons will be less than the dose constraint.

5.27. Dose constraints can be set at levels that depend on the particular facility and its location. However, national authorities may choose to develop generic dose constraints, particularly for facilities of a standardized design, with optimization used to ensure doses are below these constraints for specific facilities.

5.28. When there are several facilities on one site (e.g. in the case of multiple nuclear power plants) or along a river, each with its separate gaseous and liquid discharge outlets, the government or regulatory body should decide whether a dose constraint should be applied to the total dose to the most exposed representative person or a (lower) dose constraint should be applied to any particular facility.

5.29. A generic upper value for a dose constraint should be defined by the government or the regulatory body for different practices. Many countries have already set maximum levels of individual exposure that effectively constrain the optimization of protection for various sources. Although these values were promulgated on varying bases, they have effectively become values that are now called dose constraints. Considering the need for flexibility in the process of optimization the use of a range is advisable. Based on the experience in States this range for the dose constraint for nuclear fuel cycle facilities (including reactors) could be of annual doses of between 100 and 800 μSv. Other practices could have other ranges of generic dose constraints.

5.30. When the projected doses to the representative person are in the order or below the exemption criteria, e.g., 10 μSv in the year, a process for optimization should not be required on the basis that further dose reduction would generally not fulfil the optimization requirements.

CHARACTERIZATION OF DISCHARGES AND EXPOSURE SCENARIOS

5.31. Preoperational studies should be made to identify the inventories of radionuclides which would result in releases during operation of a facility, 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.

5.32. The need for a detailed characterization of the discharges should depend on the projected magnitude of the dose to the representative person in accordance with a graded approach.

5.33. 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.

5.34. 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]).

5.35. In the case of discharges to 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.

5.36. 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.

5.37. Pre-operational studies should also be carried out to determine the existing levels 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).

5.38. 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 NORM. Detailed guidance on undertaking pre-operational surveys is given in Refs. [8] and [20].

5.39. 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 sea or fresh water (lake or river). 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.

5.40. 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 operator 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

5.41. 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.

5.42. 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.

5.43. 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.

5.44. 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.

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

5.46. 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 were 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.

5.47. 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 operator . The discussions on optimization could also involve different authorities, for instance those responsible of nuclear safety, workers protection, public and environmental protection.

Decision aiding techniques

5.48. 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. However, when the doses to the representative person are assessed to be very low (e.g. of the order of 10 μSv 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, for NPPs or similar installations).

5.49. 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

5.50. 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 technology (or best available techniques) are used in some States [24] and under certain international frameworks [25] 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

5.51. The estimation of collective doses resulting from different options or alternatives (for example, different waste management and discharge options) and their direct comparison can be another parameter to include in the optimization process.

5.52. Collective dose is defined as the sum of doses received by members of the exposed populations from all significant exposure pathways from a given source [16, 17 and 18]. 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, limiting conditions should be set.

5.53. There could be 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 detailed guidance on the use of collective dose; however, with the adequate considerations and care, collective dose could be a practical means to apply optimization. Publication [16] discusses optimization and use of collective dose in more detail.

ASSESSMENTS OF DOSES TO REPRESENTATIVE PERSON

5.54. The establishment of an authorization of discharges should take into account the results of a previous assessment of the radiological environmental impacts [2]. [6] 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.

5.55. 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.

5.56. 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.

5.57. In order to make and effective use of assessment resources, a structured iterative approach should be used for assessing doses to the representative person group. Such an approach should start with a simple assessment based on very cautious (conservative) assumptions and is refined with each iteration using progressively more complex models with more realistic assumptions and data, as necessary.

5.58. At the time of setting the discharge limits, a site-specific assessment should normally be used for nuclear fuel cycle facilities.

5.59. The use of generic assessments is particularly useful for assessing the impacts from small facilities such as hospitals and research laboratories because discharges from such facilities are usually very low.

5.60. A generic approach also may be used to estimate doses to the representative person at the early stages in the life of a complex installations (see Fig 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.

5.61. 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 mean 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 that are likely to significantly over-estimate the doses that would be received by members of the public could lead to decisions which result in lower doses to the public but with higher costs and possibly higher doses to workers than would be optimum.

5.62. The effective dose received by members of the public depends upon a number of factors, such as the behaviour of radionuclides in the environment and their transfer to people, the duration of exposure and other relevant factors. These factors cause a wide variation in the effective dose among the exposed population. 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].

5.63. The estimated effective doses for the representative person should be based on the reference person model [17, 18]. However, the habits (e.g., consumption of foodstuffs, location, 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 overestimation. Extreme or unusual habits should not dictate the characteristics of the representative persons considered [16].

5.64. 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 [6, 12 and 13].

5.65. 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.

5.66. 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 Ref. [12] and [13]. The possible accumulation of long-lived radionuclides (with half-lives longer than say one year) should be taken into account.

5.67. 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.

5.68. 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) with the embryo or fetus and breast fed infants also being considered in some limited circumstances [16].

5.69. Further information on the representative person and the considerations for the assessments approach and modelling, including the level of detail, are discussed in [6] and [16].

5.70. 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 defined 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

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

5.72. 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.

5.73. In granting an authorization, the regulatory body should establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges. These should take account of the radiological environmental impact assessment and the results of optimization of protection and safety and should be in accordance with a graded approach – large, complex facilities such as nuclear power plants should be subject to a detailed licensing process and conditions of authorization of discharges, while the conditions associated with authorizations for discharge for less complex facilities such as hospitals or small laboratories should be less onerous. These conditions should be expressed in terms that the operator can reasonably be expected to control, for example in terms of measured discharges rather than doses to the public, which can only be estimated.

5.74. Discharge limits will be written and attached or incorporated into the authorization and will become the legal limits with which the operator or licensee should comply.

5.75. 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 installation like nuclear power plants, reprocessing facilities and radioisotopes production facilities should be at least once every five years. More simple installations like hospitals or facilities 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.

5.76. 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.

5.77. 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 weather[13]);

(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 concentrations[14];

(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 BSS [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 validity.

5.78. The discharge limits should include a margin for flexibility to provide for operational variability. 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 [9]. The need for operational flexibility should be considered as part of the optimization process in setting the discharge limits.

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

(a) The feasibility of measurement of the individual radionuclides;

[13] 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.

[14] 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.

(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.

5.80. 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. For example, airborne discharges from nuclear plants 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.

5.81. 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.

5.82. 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.

5.83. The operator should take provisions to report promptly to the regulatory body.

5.84. The operator 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.

5.85. Figure 4 illustrates the relation of source related dose constrains and authorized discharge limits.

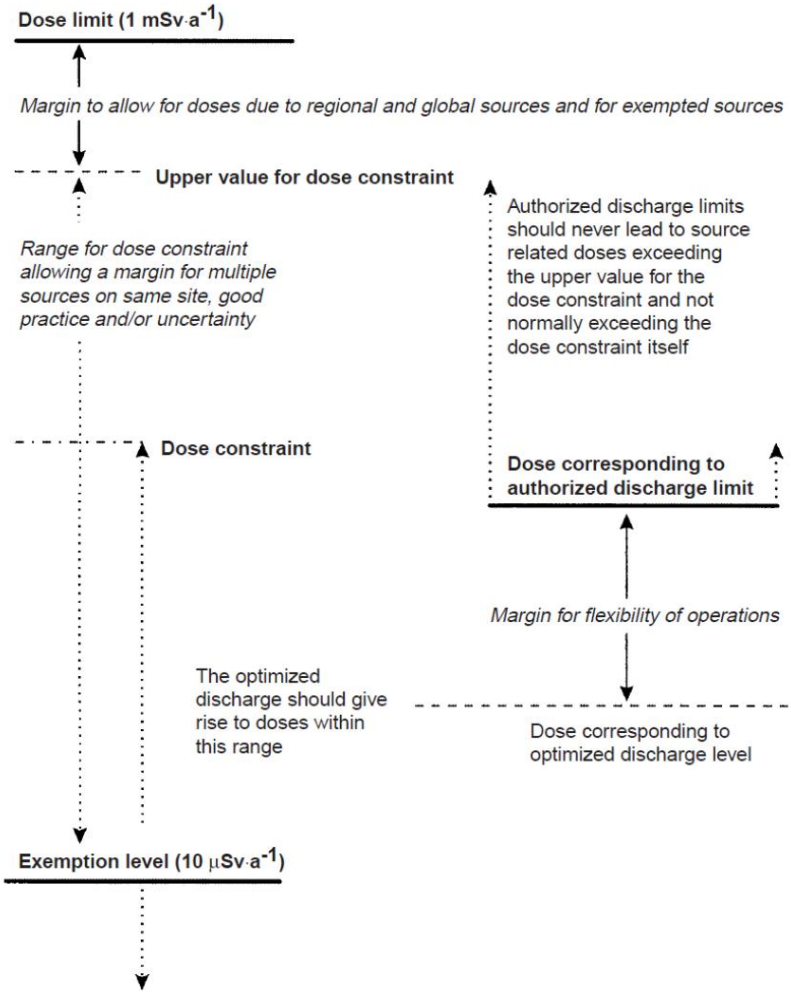

Figure 4: relation of source related dose constraints and authorized discharge limits.

5.86. A generic upper value for dose constraint can be the starting point for the process of optimization. The regulatory body should define this upper value considering a margin for doses due to regional and global sources and for other sources.

5.87. In order to define the source specific dose constraint, the existing or projected multiple sources in the same site should be considered, together with dose constraints based on similar good practices. This could also considering uncertainty.

5.88. From the specific dose constraint a process of optimization as describe in Section CONSIDERATION OF OPTIMIZATION OF PROTECTION above should be applied by the applicant and reviewed by the regulatory body, in order to define the level of dose corresponding to a discharge level optimized from the protection of the public point of view. This level should be below or equal to the specific constraint, depending on the results of the optimization.

5.89. In order to consider the possible variations in the normal operations, a margin for flexibility should be defined by the regulatory body based on the characteristics of the practice or the experience from similar installations.

5.90. In general, if the projected doses to the representative person are in the order or below the exemption criteria, e.g. in the order of 10μSv in a year, a process of optimization should not be required.

DEMONSTRATION OF COMPLIANCE

5.91. 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. For installations like nuclear power plants environmental monitoring should also provide an additional means, besides effluent monitoring, of checking for unexpected releases.

5.92. Simple installations like hospitals or small research laboratories may not need a permanent environmental monitoring programme but a single monitoring campaign close to the installation at the beginning of operations should be considered by the regulator as a requisite to verify compliance.

5.93. The requirements for monitoring should be specified in the discharge authorization by the regulatory body.

Monitoring by operator

5.94. Registrants and licensees should 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. The monitoring programmes defined by operators should be approved by the regulatory body.

5.95. Two general types of monitoring are appropriate in the context of control of discharges and the related public radiation exposure. Firstly monitoring of the source, which implies measuring activity concentration or dose rates at the discharge point or within the activity and facility and, secondly, monitoring of the environment, which involves the measurement of radionuclide concentrations in environmental media (including foodstuffs and drinking water) and dose/dose rates due to sources in the environment.

5.96. 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 and, where appropriate.

5.97. Some subsidiary objectives, which should usually be fulfilled by a monitoring programme [8], are to provide information for the public; to maintain a continuing record of the impacts of an installation or a practice on environmental radionuclide levels and to check the predictions of environmental models so as to modify them as appropriate in order to reduce uncertainties in the dose assessment.

5.98. In accordance with these general and subsidiary objectives, the monitoring programmes should include radiation and radioactivity measurements and the collection of relevant supporting information.

5.99. Monitoring programmes should be 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.

5.100. The operator 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

5.101. 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 μSv 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 operator.

5.102. 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 operator;

(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

5.103. 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.

5.104. 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

5.105. Records should be kept by the operator of the results of monitoring and verification of compliance [8]. The regulatory body should establish the characteristics and frequency of reporting those records.

5.106. 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.

5.107. Operators should report promptly to the regulatory body any levels exceeding the operational limits and conditions relating to public exposure and any significant increase in

dose rate or concentrations of radionuclides in the environment that could be attributed to the authorized practice.

5.108. Comprehensive guidance on objectives and framework for source and environmental radiation monitoring for demonstration of compliance with conditions of discharge authorization is provided in [8]. Additional technical information on programmes and systems for source and environmental monitoring is available in Ref. [20].

INSPECTION AND ENFORCEMENT

5.109. 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 operator'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.

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

5.111. Where a regulatory requirement, including a condition of the authorization, has not been met, the operator 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.

5.112. 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.

INVOLVEMENT OF INTERESTED PARTIES

5.113. In the context of this Safety Guide, the interested parties may typically include the members of the public, other States, especially neighbouring States, the media, the regulated

industry and facilities, agencies or regulatory bodies whose responsibilities may cover nuclear energy, scientific bodies and environmental groups (see Refs. [11] and [2].

5.114. Any exchange of information relating to control of discharges may form part of other decision making processes, for example in the context of the justification of a major undertaking such as a decision to construct a large nuclear facility, or as part of the planning process for construction of such facilities. 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.

5.115. 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 operator and the regulatory body. Among other things, the results of the radiological environmental impact assessment should be a focal point for the discussions.

5.116. As noted in paragraph 2.9 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 country[15].

5.117. 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 defined in the authorization issued to the operator.

5.118. 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.

5.119. 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.

[15] 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 [22].

6. FACILITIES WITH NATURALLY OCCURRING RADIOACTIVE MATERIAL

6.1. Generators of naturally occurring radioactive material (NORM) discharges 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. Where the activity concentration in the material of any radionuclide in the uranium or thorium decay chains is greater than 1 Bq/g or the activity concentration of ^{40}K is greater than 10 Bq/g the discharges should controlled according to the requirements for discharges from planned exposure situations.

6.2. In principle, the procedures for the control of discharges from NORM facilities are the same as those for practices. However there are some important differences which should be taken into account:

(a) The discharges are not usually 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 points of 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) 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;

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

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

(f) Liquid discharges from offshore oil and gas installations are unlikely to lead to significant human exposure but there may be an impact on the environment. However, the cleaning on land of pipes containing radioactive residues with elevated levels of radium may result in liquid wastes which should be controlled;

(g) 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.

6.3. In some States, facilities and activities 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.

7. DISCHARGE CONTROL 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 [Ref. will be added: IAEA GSR Part 6]. In general, two main options should be considered:

(a) Shutdown followed by immediate dismantling of the facility; or

(b) Shutdown of the facility with deferred dismantling to a later date.

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

7.3. The anticipated discharge levels following 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 dismantling, there may be an increased likelihood of low-level unplanned liquid or gaseous releases.

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

(a) The possibility of additional radionuclides being discharged that were not present in the discharge during the 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.

7.5. Dismantling of nuclear facilities usually takes place progressively over several years. Protection and safety should be optimized at each step, with account being taken of the experience gained in the previous step. Because unexpected difficulty may arise during each step, regulatory control of the discharges should follow 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 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.

8.3. If authorization of the discharge is required, similarly to a new practice, discharges should be adequately characterized, exposure pathways identified and a radiological environmental impact assessment carried out.

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. In all cases, the operator 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. 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. Licensing Process for Nuclear Installations, IAEA Safety Standards Series No. SSG-12. IAEA, Vienna, 2010.

[4] 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.

[5] INTERNATIONAL ATOMIC ENERGY AGENCY. Radiation Protection of the Public, IAEA Safety Standards Series. IAEA, Vienna. [DS432]

[6] INTERNATIONAL ATOMIC ENERGY AGENCY. Radiological Environmental Impact Assessment, IAEA Safety Standards Series. IAEA, Vienna.[DS427]

[7] INTERNATIONAL ATOMIC ENERGY AGENCY. Radiation Protection Aspects in the Design of Nuclear Power Plants, Safety Standards Series No. NS-G-1.13. IAEA, Vienna, 2005.

[8] 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.

[9] INTERNATIONAL ATOMIC ENERGY AGENCY. Setting Authorized Limits for Radioactive Discharges: Practical Issues to Consider, IAEA-TECDOC-1638. IAEA, Vienna, 2010.

[10] (Note: re-numbering later)

[11] INTERNATIONAL ATOMIC ENERGY AGENCY. IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection (2007 Edition). IAEA, Vienna, 2007.

[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] IAEA Update of SRS 19 (in preparation) IAEA Safety Report Series

[14] INTERNATIONAL ATOMIC ENERGY AGENCY. Governmental, Legal and Regulatory Framework for Safety, Safety Standards Series No. GSR Part 1. IAEA, Vienna, 2010.

[15] INTERNATIONAL ATOMIC ENERGY AGENCY. Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4. IAEA, Vienna, 2009.

[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. ICRP, Oxford and New York, 2006.

[17] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication 60, Pergamon Press (1990).

[18] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection', ICRP Publication 103, Elsevier (2007).

[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] INTERNATIONAL ATOMIC ENERGY AGENCY. Application of the Concepts of Exclusion, Exemption and Clearance, RS-G-1.7. IAEA, Vienna, 2004.

[22] 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.

[23] INTERNATIONAL ATOMIC ENERGY AGENCY. Derivation of Activity Concentration Values for Exclusion, Exemption and Clearance, Safety Reports Series No. 44. IAEA, Vienna, 2005.

[24] ENVIRONMENT AGENCY (2010), UK Principles (see https://www.gov.uk/government/policies).

[25] OSPAR, IPPC 96/61/EC

Annex

PRACTICAL CONSIDERATIONS IN SETTING DISCHARGE AUTHORIZATIONS

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

CHARACTERIZATION OF DISCHARGES

A-2. As outlined in para. xx, once the need of an authorization was confirmed the applicant should characterize the nature of that discharge, 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.

A-3. For installations using unsealed sources, such as hospitals and 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.

A-4. For existing facilities, during a periodical safety review process, information will already exist that may be reviewed to support this process [I-1]. 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

A-5. 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. 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 which should be taken into account as part of the optimization process [I-2 (ICRP 101)].

A-6. Different considerations will also be involved in optimization of proposed and existing facilities. The design stage of a new facility is likely to involve complex decisions and processes 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, due to the more limited possibilities of changing the process or activity under consideration to reduce radioactive waste than during design and, in practice, reduction in effluents is often based on an evaluation of the technical options available. Optimization of public protection for on-going discharges is often undertaken in an interactive way between the regulatory body and the operator [I-1].

A-7. 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 backfit or upgrade of the existing facility or system design features. Possible abatement techniques and control methods are discussed elsewhere [I-1].

A-8. Decision aiding techniques may 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-3] and further information is given in [I-1] in relation to the control of discharges.

A-9. 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 should also 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).

A-10. 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 the TECDOC [I-1] and some points are also given here.

A-11. An important aspect that should 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 should be included as part of the optimization process. An example of this is the application of best available techniques (best available techniques), particularly in States in Europe by commitments related to the OSPAR convention [I-4]. 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.

BEST AVAILABLE TECHNIQUES

A-12. When properly defined, best available techniques is effectively a different approach to optimization that focuses on techniques and technology rather than impact. For example within the context of IPPC, best available techniques is defined 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;

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

A-13. 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 [http://eippcb.jrc.ec.europa.eu/reference/" http://eippcb.jrc.ec.europa.eu/reference/].

FORMS OF DISCHARGE AUTHORIZATION

A-14. There are a number of ways in which authorized discharge limits can be set based on limiting either dose or quantity 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.

A-15. Some regulatory bodies prefer dose because it is viewed as a more fundamental quantity and one that underlies the system of limitation of discharges. Setting limits in terms of quantities discharged, on the other hand, is viewed by other regulatory bodies to reflect more closely the quantity that is to be controlled and measured, and is therefore more closely connected to the actions that the registrant or licensee must take to control discharges.

A-16. Expressing limits in terms of dose or quantity of radioactive material discharged does not represent a fundamental difference, but rather one of preference, because dose and quantity are directly proportional for any given site, and one can be converted to the other without difficulty. However, while a quantity of radioactive material is a measurable magnitude, dose to members of the public is always based on an assessment [I-1].

Radionuclide grouping

A-17. 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.

A-18. For larger facilities that may discharge a variety of radionuclides, limits are generally imposed on groups of nuclides that share relevant 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.

A-19. 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.

A-20. 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

A-21. 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 large reactor site, each unit may be a nuclear reactor. In nearly all cases, regulatory bodies impose a site limit, whether or

not individual unit limits are imposed, but in some cases regulatory bodies impose only a site limit, with no limits on individual units [I-1].

Time interval for demonstrating compliance

A-22. 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.

A-23. Although annual discharge limits are almost invariably used and are considered as the primary means of regulatory control, some regulatory bodies view one year as too long a period over which is to demonstrate compliance. One concern is that the validity of the assumptions used in setting annual discharge limits may not be applicable for short-term discharges.

A-24. 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 regulator 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-1].

Operational flexibility

A-25. Based on the optimized discharge levels or operational experience the regulatory body will set authorized discharge limits. Exceeding limits will normally initiate regulatory action. There is therefore a need to allow for operational flexibility, and anticipated fluctuations in performance, 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.

A-26. Authorized discharge limits are generally set higher than the optimized levels [I-1], although within the specified dose constraints, by an amount sometimes referred to as 'headroom' (or allowance for operational flexibility). How much operational flexibility (or headroom) 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 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 should be permitted.

A-27. 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-1].

Period of validity of the discharge authorization

A-28. Some regulatory bodies issue discharge authorizations that have a limited period of validity. At the end of the period of validity, authorizations are reviewed, and updated, if necessary, based on current information. 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 defined limit on the validity of the discharge authorization.

A-29. It is usual to require facilities 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 review.

A-30. In some cases, the period of validity of the authorization may be equal the expected design life of the facility. Such facilities 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 critical group 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] INTERNATIONAL ATOMIC ENERGY AGENCY. Setting authorized limits for discharges: practical issues to consider. TECDOC 1638, IAEA, Vienna (2010)

[I-2] 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-3] INTERNATIONAL ATOMIC ENERGY AGENCY, Optimization of Radiation Protection in the Control of Occupational Exposure, Safety Reports Series No. 21, IAEA, Vienna (2002).

[I-4] 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).

http://www.ospar.org/eng/html/welcome.html

[I-5] OSPAR COMMISSION FOR THE PROTECTION OF THE MARINE ENVIRONMENT OF THE NORTH-EAST ATLANTIC, PARCOM Recommendation 91/4 of 20 June, 1991 On Radioactive Discharges (1991).

HYPERLINK "http://www.ospar.org/v_ospar/strategy.asp?v0=5&lang=1" http://www.ospar.org/v_ospar/strategy.asp?v0=5&lang=1

[I-6] EUROPEAN UNION, Integrated Pollution Prevention and Control (IPPC) Directive, EU, Brussels (1996).

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