IAEA SAFETY STANDARDS SERIES

REGULATORY CONTROL OF RADIOACTIVE DISCHARGES TO THE ENVIRONMENT

SAFETY GUIDE

No. WS-G-2.3

INTERNATIONAL
ATOMIC ENERGY AGENCY
VIENNA

IAEA SAFETY RELATED PUBLICATIONS

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Information on the IAEA's safety standards programme (including editions in languages other than English) is available at the IAEA Internet site

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REGULATORY CONTROL OF RADIOACTIVE DISCHARGES TO THE ENVIRONMENT

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

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FOREWORD

by Mohamed ElBaradei
Director General

One of the statutory functions of the IAEA is to establish or adopt standards of safety for the protection of health, life and property in the development and application of nuclear energy for peaceful purposes, and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under any bilateral or multilateral arrangement, or, at the request of a State, to any of that State's activities in the field of nuclear energy.

The following advisory bodies oversee the development of safety standards: the Advisory Commission on Safety Standards (ACSS); the Nuclear Safety Standards Advisory Committee (NUSSAC); the Radiation Safety Standards Advisory Committee (RASSAC); the Transport Safety Standards Advisory Committee (TRANSSAC); and the Waste Safety Standards Advisory Committee (WASSAC). Member States are widely represented on these committees.

In order to ensure the broadest international consensus, safety standards are also submitted to all Member States for comment before approval by the IAEA Board of Governors (for Safety Fundamentals and Safety Requirements) or, on behalf of the Director General, by the Publications Committee (for Safety Guides).

The IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA. Any State wishing to enter into an agreement with the IAEA for its assistance in connection with the siting, design, construction, commissioning, operation or decommissioning of a nuclear facility or any other activities will be required to follow those parts of the safety standards that pertain to the activities to be covered by the agreement. However, it should be recalled that the final decisions and legal responsibilities in any licensing procedures rest with the States.

Although the safety standards establish an essential basis for safety, the incorporation of more detailed requirements, in accordance with national practice, may also be necessary. Moreover, there will generally be special aspects that need to be assessed by experts on a case by case basis.

The physical protection of fissile and radioactive materials and of nuclear power plants as a whole is mentioned where appropriate but is not treated in detail; obligations of States in this respect should be addressed on the basis of the relevant instruments and publications developed under the auspices of the IAEA.

Non-radiological aspects of industrial safety and environmental protection are also not explicitly considered; it is recognized that States should fulfil their international undertakings and obligations in relation to these.

The requirements and recommendations set forth in the IAEA safety standards might not be fully satisfied by some facilities built to earlier standards. Decisions on the way in which the safety standards are applied to such facilities will be taken by individual States.

The attention of States is drawn to the fact that the safety standards of the IAEA, while not legally binding, are developed with the aim of ensuring that the peaceful uses of nuclear energy and of radioactive materials are undertaken in a manner that enables States to meet their obligations under generally accepted principles of international law and rules such as those relating to environmental protection. According to one such general principle, the territory of a State must not be used in such a way as to cause damage in another State. States thus have an obligation of diligence and standard of care.

Civil nuclear activities conducted within the jurisdiction of States are, as any other activities, subject to obligations to which States may subscribe under international conventions, in addition to generally accepted principles of international law. States are expected to adopt within their national legal systems such legislation (including regulations) and other standards and measures as may be necessary to fulfil all of their international obligations effectively.

EDITORIAL NOTE

An appendix, when included, is considered to form an integral part of the standard and to have the same status as the main text. Annexes, footnotes and bibliographies, if included, are used to provide additional information or practical examples that might be helpful to the user.

The safety standards use the form 'shall' in making statements about requirements, responsibilities and obligations. Use of the form 'should' denotes recommendations of a desired option.

The English version of the text is the authoritative version.

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1. INTRODUCTION

BACKGROUND

1.1. In 1995, the International Atomic Energy Agency (IAEA) published the Safety Fundamentals entitled 'Principles of Radioactive Waste Management' [1] (Waste Safety Fundamentals). The application of these principles requires the implementation of measures that will afford protection of human health and the environment, since improper management of radioactive waste could result in adverse effects on human health or the environment, now and in the future.

1.2. In 1996, the IAEA, jointly with five other sponsoring international organizations, published the Safety Fundamentals on 'Radiation Protection and the Safety of Radiation Sources' [2] (Radiation Safety Fundamentals), which define principles whose effective application will ensure appropriate protection of people in any situation which involves or might involve exposure to ionizing radiation. Basic requirements for protection against the risks associated with exposure to ionizing radiation (hereinafter called 'radiation') and for the safety of radiation sources are specified, together with some guidance on how to apply them, in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [3]. These Standards, issued in 1996, are based on the Radiation Safety Fundamentals, the recommendations of the International Commission on Radiological Protection (ICRP) [4] and, for the purposes of this Safety Guide, on relevant material in the IAEA Safety Series (Refs [5–7] among others).

1.3. The present Safety Guide is concerned with the regulatory control of radioactive discharges to the environment during normal, controlled operation of practices involving the use of radioactive material. It expands on and interprets the principles stated in both the Waste Safety Fundamentals [1] and the Radiation Safety Fundamentals [2], and elaborates on the requirements specified in relevant IAEA safety standards [3, 8, 9] that relate to the control of such discharges to the environment.

OBJECTIVE

1.4. The purpose of this Safety Guide is to describe how to apply the Waste Safety Fundamentals, the Radiation Safety Fundamentals and the BSS in the control of

discharges of radionuclides to the environment from the normal operation of practices and sources within practices. It provides a regulatory body (as defined in para. 2.2) with a structured approach to the limitation of risk to members of the public and optimization of protection from such operations, which may be adapted to the specific legal and regulatory infrastructure within which such a body operates. It also gives guidance on the responsibilities of registrants and licensees in conducting radioactive discharge operations.

SCOPE

1.5. The scope of this Safety Guide is limited to discharges to the environment of radioactive substances in the form of airborne (gases, aerosols) or liquid effluents from the normal operation of practices and sources within practices. The sources considered range from radionuclides used for medical and research purposes to nuclear reactors and reprocessing facilities. The term 'discharge' is used in this Safety Guide to refer to the ongoing or anticipated releases of radionuclides arising from the normal operation of a practice or a source within a practice. Discharges to atmosphere and discharges directly to surface water bodies are considered, but discharges of liquid radioactive substances by injection deep underground and releases arising from accidents are not considered. Discharges from uranium mining and milling facilities and from the disposal of solid radioactive waste are not considered. Specific guidance on these matters is given elsewhere (e.g. Refs [6, 10]).

1.6. Guidance is given for setting discharge limits for new sources as well as for existing sources in order to bring them within the requirements of the Fundamentals and the BSS. This Safety Guide makes reference to the assessment models and data described in a companion publication [11]. Emphasis is placed upon the optimal use of resources, including those of the regulatory body. Discharge limits would be included in, or would accompany, an authorization issued by the regulatory body which allows operation. The authorization can be in the form of a registration, a licence or similar document; guidance is given on which of these forms of authorization may be appropriate under different circumstances.

1.7. An additional principle of the Waste Safety Fundamentals is that radioactive waste be managed in such a way as to provide an acceptable level of protection of the environment. This includes the protection of living organisms other than humans and also the protection of natural resources, including land, forests, water and raw materials, together with a consideration of non-radiological environmental impacts. This Safety Guide is concerned only with control measures to protect human health.

Guidance on protecting the environment from ionizing radiation is being developed by international organizations, including the IAEA.

STRUCTURE

1.8. The general regulatory approach for protection of the public from radionuclides discharged during normal operation is described in Section 2. The recommended approach to setting discharge limits for new sources is described in Section 3 and the appropriate procedures for maintaining control during operation are contained in Section 4. A procedure for bringing existing practices within the principles and requirements of the Fundamentals and Standards is recommended in Section 5. Considerations in establishing a generic dose constraint for members of the public are set out in the Appendix. Background material explaining the underlying radiological protection concepts relevant to this document is contained in the Annex.

2. GENERAL RESPONSIBILITIES

2.1. Section 2 sets out the general responsibilities incumbent upon the regulatory body and the registrant/licensee (e.g. the organization/company operating the facility) in the context of discharging radionuclides to the environment. The following paragraphs are based mainly on the BSS [3]; they are generally consistent with the requirements of Ref. [8].

THE REGULATORY BODY

2.2. The BSS "are based…on the presumption that a national infrastructure is in place enabling the Government to discharge its responsibilities for radiation protection and safety" (Ref. [3], Preamble). An essential part of a national infrastructure is a regulatory body empowered to authorize and inspect regulated activities and to enforce the national legislation and regulations.

2.3. The regulatory body may comprise one or more bodies designated or otherwise recognized by the Government for regulatory purposes. The regulatory body should be granted sufficient powers and resources for effective regulation and should remain independent of any government department and agencies that are responsible for the promotion and development of the practices being regulated. It should also

be independent of registrants, licensees and the designers and constructors of radiation sources used in practices [3].

2.4. The functions of the regulatory body which are relevant to the discharge of radioactive effluents include: preparation of regulations; review of applications to discharge radioactive materials to the environment; approval or rejection of these applications and the granting of authorizations; the conduct of periodic inspections to verify compliance; and enforcement against any violations of regulations, standards and licence conditions. The effectiveness of radiation protection measures for each authorized discharge, together with the potential impact of this discharge on humans and the environment, should also be assessed.

2.5. The powers of the inspectors of the regulatory body should be well defined and consistency of enforcement should be maintained, with provision for appeal by those responsible for the discharge of radioactive effluents. Directives to both inspectors and regulated legal persons should be clear.[1]

2.6. The regulatory body may need to provide guidance on how certain regulatory requirements are to be fulfilled for various practices, for example, in regulatory guideline documents. An attitude of openness and co-operation should be fostered between regulated legal persons and inspectors, which includes facilitating access by inspectors to premises and to information.

ADMINISTRATIVE RESPONSIBILITIES

2.7. Practices should be introduced, conducted or discontinued only in accordance with the appropriate national requirements. Any legal person intending to undertake any of these actions "shall submit a notification to the regulatory body of such an intention" (Ref. [3], para. 2.10) and shall apply to the regulatory body for an authorization which may take the form of either a *registration* or a *licence* [3].

2.8. There are circumstances in which notification (and therefore also authorization) is not required: exposures may be excluded, and practices or sources may be exempted from the regulatory requirements [3].

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[1] 'Legal person' is defined in the BSS as "Any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action taken under these Standards."

2.9. *Exclusion* refers to "any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of the Standards" (Ref. [3], para. 1.4). A specific example relevant to this Safety Guide is the gaseous discharge, through a building ventilation system, of radon and associated progeny arising from the ground or from construction materials.

2.10. *Exemption* from the regulatory requirements is also possible for particular practices or sources within a practice. It is recognized internationally that regulatory systems may need to include provisions for granting exemptions if it is clear that the practice is justified but regulatory provisions are unnecessary or unwarranted. Briefly, the general principles for exemption are that the radiation risks to individuals and populations caused by the exempted practice or source are sufficiently low as to be of no regulatory concern and that the exempted practices and sources are inherently safe. In particular, "a (justified) practice or a source within a (justified) practice may be exempted without further consideration provided that the following criteria are met in all feasible situations:

(a) The effective dose expected to be incurred by any member of the public due to the exempted practice or source is of the order of 10 μSv or less in a year[2], and
(b) Either the collective effective dose committed by one year of performance of the practice is no more than about 1 man Sv, or an assessment for the optimization of protection shows that exemption is the optimum option." (Ref. [3], Schedule 1, para. I–3).

The exempted practices and sources should also be inherently safe, with no appreciable likelihood of scenarios that could lead to a failure to meet the criteria in (a) and (b).

Exemption of a practice or source covers all discharges of radionuclides from that practice or source.

2.11. Sources, including substances, materials and objects, within notified or authorized practices may be released from further regulatory requirements subject to complying with *clearance levels* approved by the Regulatory Authority [3]. The concept

[2] For the purpose of the specific practical guidance given in the following, a value of 10 μSv in a year is used.

of *clearance* is also based on the principle that sources can be released from regulatory requirements provided that it can be demonstrated that they present trivial risks to individuals and populations. However, clearance applies to sources *already within regulatory control* and therefore it may be relevant to the relinquishment of control over regulated discharges when, owing to a change of circumstances (e.g. a decrease in waste production or radioactive decay after storage), they fulfil the criteria for clearance.

2.12. *Notification* of an intended practice to the Regulatory Body by the legal person is sufficient in those cases in which the normal exposures associated with the practice or source are unlikely to exceed a small fraction, specified by the regulatory body, of the relevant limits, and the likelihood and expected amount of potential exposure and any other detrimental consequences are negligible [3]. This can usually be judged on the basis of previous experience or a preliminary qualitative assessment. In this case, notification requires no more on the part of the regulatory body than a simple acknowledgment.

2.13. For practices or sources involving a more significant risk, a formal *authorization* by the regulatory body is required. The authorization is a permission granted in a document by the regulatory body to a legal person who has submitted an application to carry out a practice and, in particular, to discharge radioactive materials to the environment. Any legal person applying for an authorization, including for the discharge of radioactive effluents, should submit to the regulatory body the relevant information necessary to support the application. The application should contain an assessment of the nature, magnitude and likelihood of the exposures attributed to the discharges and, when required, an appropriate safety assessment, including an explanation of how radiological protection has been optimized. This information should be submitted prior to the commencement of the practice and its discharges, and the legal person applying should refrain from carrying out the operation until a registration or a licence, as appropriate, has been granted [3].

2.14. The application for an authorization should be considered by the regulatory body, which may grant or refuse an authorization or may impose whatever conditions or limitations it deems appropriate (see Sections 3 and 4). Authorized discharge limits may be included in an authorization issued by a regulatory body permitting the start of a practice or use of a source. Alternatively they may be issued in the form of a separate document and referred to as a ‘discharge authorization’.

2.15. The authorization may take the form of either a registration or a licence. One input to the choice of whether registration or licensing is appropriate for a practice or source is the assessed risk to members of the public from the discharge of

radioactive effluents in normal operations (see Section 3). *Registrations* can be granted for practices with low to moderate associated risks[3], and are usually expressed in somewhat generic terms but may have specific conditions or limitations attached. For example, registration may be viewed as appropriate for a moderately sized nuclear medicine department using radionuclides for diagnostic purposes. A licence is accompanied by specific requirements and conditions that should be complied with by the licensee. For discharges to the environment, these conditions could take the form of annual and shorter term limits on the discharges of particular radionuclides or an appropriately weighted sum of them. In general, the requirements for the safety assessment and the conditions or limitations applied to the radioactive discharges from a practice or source should be more stringent for licensing than for registration. In the case of any nuclear installation or radioactive waste management facility, or any other practice or source which the regulatory body has not designated as suitable for registration, the BSS specify that the authorization shall take the form of a licence.

REGISTRANTS AND LICENSEES

2.16. Registrants and licensees (i.e. the legal persons that applied for the authorization) are responsible for setting up and implementing the technical and organizational measures that are necessary for ensuring the protection of the public in relation to the radioactive discharges for which they are authorized. In particular, they are responsible for implementing any conditions or limitations specified by the regulatory body in an authorization. Registrants and licensees may appoint other people to carry out actions and tasks related to these responsibilities, but they should retain the responsibility for the actions and tasks themselves.

2.17. The BSS require that "Registrants and licensees shall notify the Regulatory Body of their intentions to introduce modifications to any practice or source for which they are authorized, whenever the modifications could have significant implications for protection or safety, and shall not carry out any such modifications unless specifically authorized by the Regulatory Body." (Ref. [3], para. 2.16).

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[3] "Typical practices that are amenable to registration are those for which: (a) safety can largely be ensured by the design of the facilities and equipment; (b) the operating procedures are simple to follow; (c) the safety training requirements are minimal; and (d) there is a history of few problems with safety in operations. Registration is best suited to those practices for which operations do not vary significantly." (Ref. [3], footnote to para. 2.11).

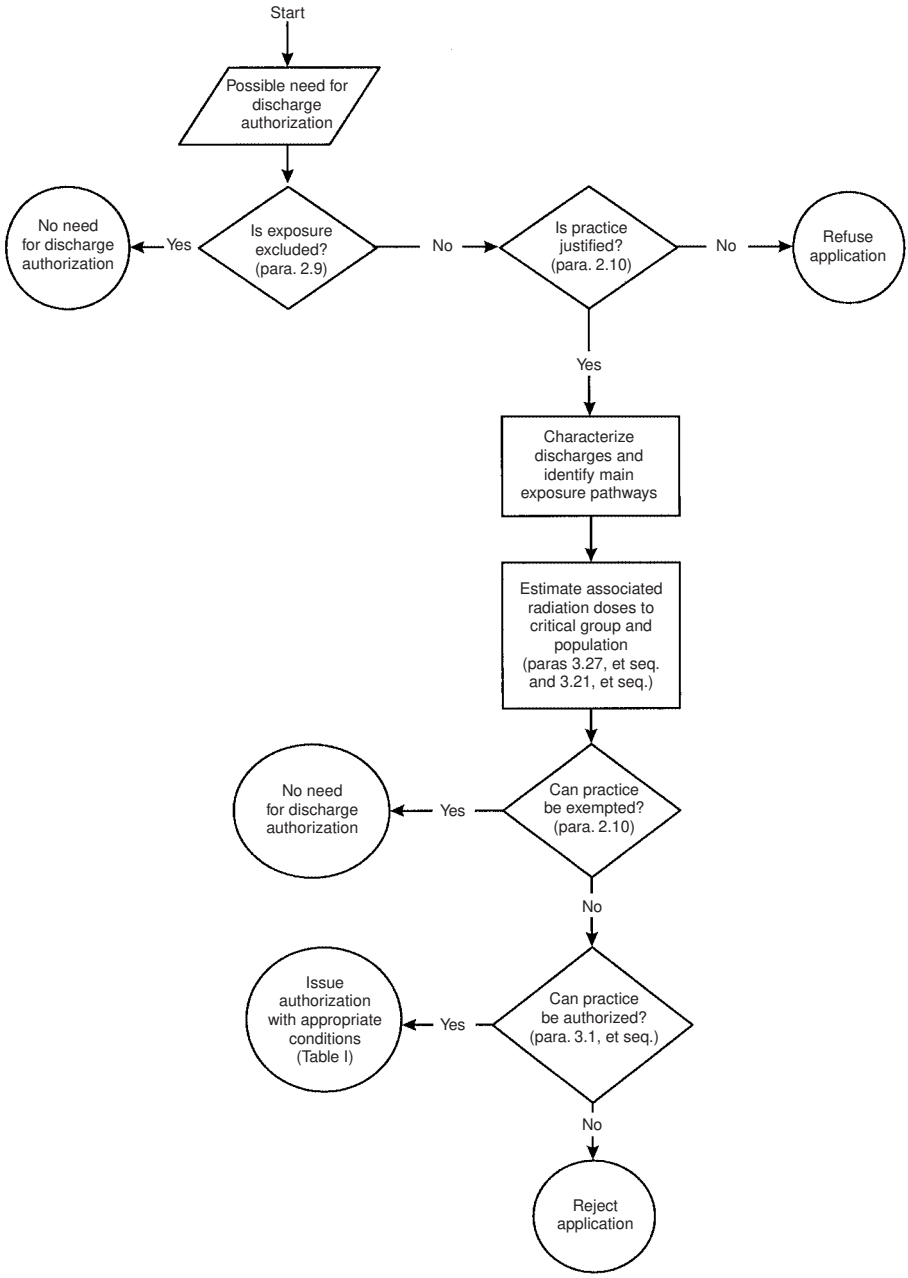

FIG. 1. Illustrative scheme for developing a discharge authorization.

3. AUTHORIZATION OF DISCHARGES FOR A NEW PRACTICE OR SOURCE

3.1. Section 3 covers the points that should be considered in authorizing discharges and setting any appropriate specific conditions for a new practice or source relating to those discharges (including setting discharge limits).

3.2. A structured approach for deciding on the level of regulatory control necessary in relation to practices involving discharges of radionuclides to the environment is set out in the following paragraphs and in Fig. 1. The procedure is intended as an aid to the optimum use of regulatory resources. For small users (e.g. small radioisotope research laboratories), where usage of radionuclides and the corresponding discharges are very low and the source is inherently safe, a simple standard discharge authorization with very few conditions will normally be adequate. For other sources (e.g. a nuclear reactor), a discharge authorization containing appropriate conditions (including specific discharge limits) will be necessary and will be attached to a licence.

ESTABLISHING THE NEED FOR A DISCHARGE AUTHORIZATION

3.3. There are some situations for which an authorization specifying discharge limits will not be necessary. These are situations in which the exposures can be excluded or the source can be exempted.

3.4. Once a proposed source or practice has been identified, the first step is to establish whether the associated exposures are excluded from the regulatory requirements (see para. 2.9). If so, no further action is required; specifically, there is no requirement to notify the regulatory body.

3.5. If the exposures are not excluded, the next step is to decide whether the practice is justified. There are many factors to be considered in such a decision, including the magnitude of the detriment associated with any discharges. Practices deemed not to be justified should not be allowed. However, decisions on justification are not usually the sole responsibility of the regulatory body for radiation protection (see para. A–13 of the Annex).

3.6. Some justified practices or sources may be exempted from some or all of the regulatory requirements, including those for notification, registration or licensing [3]. In particular, regulatory bodies can exempt practices or sources from the need for

authorization and regulatory control of radioactive discharges if, after following the dose assessment procedures outlined in the following, it is established that the basic radiological protection criteria for exemption are met (see para. 2.10). Regulatory bodies could also grant clearance for discharges from already authorized or notified sources within practices if the dose assessment procedures outlined in the following confirm that the basic radiological protection criteria for clearance are met (see para. 2.11). For some other justified practices or sources, notification to the regulatory bodies may in itself be sufficient (see para. 2.12). For practices or sources whose discharges do not satisfy the criteria for notification (see para. 2.12), the regulatory body may issue a discharge authorization (see para. 2.13) or may reject the application to discharge.

DEVELOPMENT OF A DISCHARGE AUTHORIZATION

3.7. In cases where exclusion, exemption or clearance do not apply or where notification in itself is not sufficient, "Registrants and licensees, before initiating the discharge to the environment…, shall, as appropriate:

(a) Determine the characteristics and activity of the material to be discharged, and the potential points and methods of discharge;
(b) Determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides can deliver public exposure;
(c) Assess the doses to the critical groups[4] due to the planned discharges; and
(d) Submit this information to the Regulatory Body as an input to the establishment of authorized discharge limits and conditions for their implementation." (Ref. [3], para. III.10).

3.8. The submission should also address the issues of waste generation[5] and management interdependences[6], i.e. principles 7 and 8 in the Waste Safety Fundamentals [1] as well as similar requirements in Appendix III, para. III.8 of the BSS [3]. In this regard, the submission should demonstrate that registrants and licensees will ensure that the generation of radioactive wastes in terms of activity and volume is kept to the mini-

[4] The concept of a critical group is described in para. A–15 of the Annex and further elaborated in paras 3.33 and 3.34.

[5] "Generation of radioactive waste shall be kept to the minimum practicable."

[6] "Interdependences among all steps in radioactive waste generation and management shall be appropriately taken into account."

mum practicable and that available options for waste disposal are taken into account to ensure that discharge to the environment is an acceptable option. Therefore, different possible operational regimes will need to be considered in the submission, together with their associated discharge levels and any anticipated fluctuations during normal operation.

3.9. The remainder of Section 3 sets out in detail the information that should be contained in the submission, how it should be obtained and the way it should be used to carry out the iterative process necessary to set a discharge authorization. The overall objective of the exercise is not merely to ensure compliance with the requirements set out by the regulatory body, but also to ensure that the discharges to the environment are part of a well managed and well designed operation.

3.10. The first stage of this process is to characterize the planned discharges, as appropriate, in terms of:

— Radionuclide composition;
— Chemical and physical form of the radionuclides, particularly if this is important in terms of environmental or metabolic behaviour;
— Routes of discharge and discharge points;
— Total amount of the various radionuclides expected to be discharged per year;
— Expected time pattern of discharge, including the need for and likelihood of enhanced short term discharges.

3.11. The necessity for a detailed radionuclide specific characterization of discharges depends in part upon the projected critical group dose.

3.12. The source term may be characterized by different methods. For installations using unsealed sources, such as hospitals and research laboratories, discharges can be assessed on the basis of the estimated throughput, with allowance made for radioactive decay. For power reactors and nuclear fuel cycle facilities, estimates of discharges can be made from a consideration of the design and proposed operating characteristics. Comparisons with similar installations already in operation elsewhere may also provide a valuable source of information on possible discharges (see e.g. Ref. [12]).

Optimization of protection

3.13. The next step is to establish which operational mode and associated discharge level is optimal in radiological protection terms. This is an important stage in the process of developing a discharge authorization. An evaluation should be made of the

costs and efficacies of available control options and of the possibility of changing the process or activity under consideration such that radioactive waste is not generated, or that at least its generation is reduced to the minimum practicable.

3.14. For routine discharges of radioactive materials to the environment, the main types of control options are to provide either storage facilities for gaseous and liquid effluents, so that short lived radionuclides can decay before release, or treatment facilities that remove radionuclides from the effluent stream for disposal by other means. 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, including capital, operating and maintenance costs, the implications for waste management, and the effect on individual and collective doses for both the public and workers. There may be a number of complex trade-offs between these various features. These include the following:

— Trade-off between doses to the public and doses to the workers involved in waste treatment and disposal operations;
— Trade-off between present doses resulting from effluent discharges and future doses associated with the discharges and with the disposal of solid waste resulting from solidification of those effluents;
— Choice between options whose characteristics are known with different degrees of certainty.

These are probably best handled by decision aiding techniques that take account of all relevant criteria.

Setting dose constraints

3.15. The regulatory body is responsible for specifying the value of dose constraints, although registrants or licensees may additionally specify them in their internal rules. In any case, those who establish constraints should clearly describe the relevant source, and the magnitude of the constraint selected should be appropriate to the purpose in hand.

3.16. The choice of a value for a dose constraint should reflect the need to ensure that a critical group dose, both now and in the future, is unlikely to exceed the dose limit, with account taken of contributions of dose expected to be delivered by all other practices or sources to which the critical group is also exposed. More generally, the choice of the dose constraint should "ensure, for any source (including radioactive waste management facilities) that can release radioactive substances to the environment, that the cumulative effects of each annual release from the source be restricted so that

the effective dose [and relevant organ or tissue doses] in any year to any member of the public, including people distant from the source and people of future generations, is unlikely to exceed any relevant dose limit, taking into account cumulative releases and the exposures expected to be delivered by all other relevant sources and practices under control." (Ref. [3], para. 2.26(b)).[7]

The dose constraint should, therefore, be set below the annual dose limit for members of the public.

3.17. Before specifying the dose constraint, experience from well managed operations in other comparable practices should also be taken into account. The final choice will 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. The choice may also be affected by political and social considerations and other reasons not to exceed a given level of individual dose [13].

3.18. The regulatory body will normally set dose constraints at different levels depending on the particular practice. It will make allowances for unknown future practices, exempted sources and the possibility of changes in critical group habits, and will take into account experience from well managed operations. A suggested generic upper value for a dose constraint for public exposure is derived in the Appendix.

Process for optimizing protection

3.19. Guidance on the optimization of radiological protection is given in Ref. [14]. The initial step in optimizing is to ensure that the doses to the critical group due to the discharges anticipated, with the control options considered, comply with the dose constraint. Any control option that does not satisfy this condition would normally be excluded from the optimization process. Guidance on undertaking the appropriate critical group dose assessments is given in paras 3.27–3.29. Other relevant factors should be considered at this stage; for example, the existence of limits on non-radioactive contaminants. Protection is then optimized by choosing, from among the

[7] In the 1980s, it was proposed that the exposure of individuals due to given sources should be limited to a fraction of the dose limit (called in the past the 'source-related dose upper bound'), such that the sum of the contributions of the exposure of those individuals from several sources could not exceed the dose limit. While this apportionment of the limit belongs to the principle of limitation of individual doses and is conceptually different from the establishment of constraints for the optimization of given sources, the numerical values of constraints should be less than or at most equal to that of the source upper bound [13].

control options which satisfy the dose constraint condition, the one for which radiation doses are as low as reasonably achievable, economic and social factors being taken into account.

3.20. Formal decision aiding techniques may be used in the optimization process, including cost–benefit analysis and multicriteria methods. In the case of *registered* facilities, a formal analysis of the optimization of protection from routine discharges is usually not necessary owing to the normally low doses to the public. Sources considered to be in this category are those involving quantities of radionuclides being used in research institutes or in nuclear medicine departments for diagnostic purposes. However, *licensed* facilities (such as nuclear reactors, reprocessing facilities and radioisotope production facilities) do require a full study of the optimization of protection from discharges.

3.21. One input into formal studies of the optimization of protection is the collective dose to the exposed population. However, some of the components of collective dose may be characterized by substantial uncertainty. In particular, when radiation exposures from very long lived nuclides persist into the far future, the assessment of the total collective dose is highly speculative and this may invalidate the results of the analysis. In optimization, however, it is the differences between collective doses for different control options which should be considered. The period of interest for the optimization analysis is, therefore, only the period in which the alternative control options have different influences on the exposure pattern.

3.22. In order to decide by means of the optimization process whether a reduction in the proposed discharges may be indicated and to choose the appropriate control option, the following initial screening procedure is recommended. Data and models given in Ref. [11] enable an estimate to be made of the collective dose commitment in man Sv arising from discharges in a year. This should be added to an estimate of the relevant collective dose from occupational exposure to provide an estimate of the total collective dose. If this value is less than about 1 man Sv, there is no need to carry out an extensive formal optimization study as it is very unlikely to be worthwhile [7]. The overall objective is to avoid spending resources to assess options for reducing discharges in disproportion to the likely improvement in radiological protection.

3.23. If the value is greater than about 1 man Sv in a year, a formal study is required with the use of decision aiding techniques such as *cost–benefit analysis* and *multicriteria methods.* The objective of using cost–benefit analysis to optimize protection is to identify the level of protection that minimizes the sum of the cost of protection and the cost of radiation detriment. The cost of the health detriment is assumed to be

proportional to the collective dose. In order to apply cost–benefit analysis to the optimization of protection, the cost of protection and the cost of radiation detriment should both be expressed in monetary terms. The estimation of costs of protection is in principle a straightforward procedure, although considerable complexities may arise when detailed costs of plant, materials, energy and labour need to be considered. Assigning a cost to radiation health detriment requires a judgement by the regulatory body of the value of avoiding the deleterious effects of radiation exposure. Appropriate monetary values for unit collective dose are given in Ref. [14]. In some cases, the regulatory body may need to exercise judgement on the possible need to assign different costs to parts of the collective doses that occur over different time periods, especially when a practice leads to environmental contamination by long lived radionuclides and therefore to exposures among future generations.

3.24. In some cases, the radioactive discharges from a source in a given country can cause public exposure in another country. In such cases, the component of the cost of radiation health detriment due to the collective dose incurred outside the source country should be assessed by using a monetary value of unit collective dose which is not lower than the value applied within the source country.

3.25. 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. Multicriteria 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, for the radiological impact, 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 multicriteria methods. The distributions over time of investments and operating costs can also be considered. Other useful inputs may be technical factors such as the flexibility and redundancy of a proposed installation or process, its development status, and the extent of technical support or of the research and development effort.

3.26. The outcome of the optimization process is the identification of the radiological optimum control option and its associated discharge levels. After these studies have been performed, regulatory bodies may wish to take into account typical discharges from similar well managed installations elsewhere. Such considerations may provide verification of the results of the optimization process.

Assessment of critical group doses

3.27. One of the fundamental components of the optimization analysis is the assessment of the dose to individuals of the critical group for each of the discharge options

considered and the verification that this dose does not exceed the appropriate dose constraint. A structured iterative screening approach should be used for assessing doses to the critical group. Such an approach starts with a simple assessment based on very conservative assumptions and is refined with each iteration using progressively more complex models with more realistic assumptions, as necessary. This approach is an effective way of using assessment resources. Moreover, it usually allows for each subsequent iteration to be targeted to those components of the assessment that give the highest contribution to the doses assessed. It calls, therefore, for priority attention in replacing very pessimistic assumptions with more realistic ones. This approach is described in detail in Ref. [11], which provides methods for the screening of planned routine discharges of radionuclides to the environment in order to comply with the relevant dose limiting criteria specified by the regulatory body.

3.28. If the dose assessed using simple models exceeds a reference level of around 10% of the value of the dose constraint, it becomes necessary to decide whether to refine the assessment in the expectation that the assessed dose can be reduced to below that specified level, or whether not to refine the assessment and, consequently, to accept more stringent conditions in the discharge authorization.[8]

3.29. The estimated critical group dose should be the maximum annual dose with any buildup of radioactive material in the environment taken into account. For this purpose, the dose estimated should normally be the annual dose in the final year of operation of the practice or source. This can be calculated as the incomplete dose commitment from one year of operation over the duration of the practice (see paras A–7 and A–8 of the Annex).

'No dilution' dose assessment model

3.30. A very simple model, using the highly conservative assumption that all exposure pathways originate at the point of discharge, can be used as the first step of this iterative screening process to make an initial upper estimate of critical group doses. As an example, the dose to a hypothetical person continuously breathing the undiluted airborne effluents from a stack or who obtains all drinking water directly from the undiluted liquid effluents at the point of discharge into a water body could be estimated. Reference [11] provides equations and 'default' values for the parameters

[8] A figure of 10% of the constraint is chosen so as to reflect the order of magnitude of the uncertainty typically associated with the predictions of the simple models [11].

needed for this extremely conservative yet simple assessment. If the maximum annual dose assessed in this way is less than the reference level, this simple assessment would suffice for radiological protection purposes. This will often be the case for small users (e.g. small radioisotope research laboratories, small diagnostic nuclear medicine departments).

Generic environmental dose assessment model

3.31. If the annual maximum dose assessed with the above mentioned discharge point model is greater than the reference level, the next step of the iterative screening approach described in Ref. [11] should be applied. This is the adoption of a less conservative, yet still cautious, model which introduces into the assessment the process of atmospheric or aquatic dispersion and the resulting exposure pathways using generic and conservative values for the relevant quantitative parameters. For example, generic models for the transport of radionuclides in the atmosphere and in water bodies are used, and conservatively biased default values are assumed for the human behaviour and dietary habits of members of the hypothetical critical group. It is also assumed, as a first approximation, that the critical group dose is the sum of the doses via all discharge routes and pathways. Under almost all circumstances, this generic assessment is expected to result in an overestimate of the actual dose to the critical group.

Site specific dose assessment model

3.32. If the annual maximum dose to the critical group assessed by using the above mentioned generic environmental model is greater than the reference level, a site specific assessment of critical group doses is required. In a site specific study, a survey of the actual distribution and habits of the population and the human utilization of environmental media to be affected by radioactive discharge from the proposed installation should be made to identify which actual exposure pathways are relevant. The study should also take into account site specific parameters for atmospheric and aquatic dispersion and for transfer of radionuclides through foodchains. The resulting information will serve to identify potential critical groups.

3.33. The critical group concept is generally described in para. A–15 of the Annex. More particularly, in the present case, the critical group should be defined with regard to food consumption rates and other lifestyle habits, and its location relative to the point of discharge or source of direct exposure. The group should be small enough to be relatively homogeneous with respect to age, diet, living and environmental conditions and those aspects of behaviour that affect the doses received. The size of the critical group for a particular site will usually be up to a few tens of individuals, although larger critical groups have been identified in some cases.

3.34. In situations where no critical group as such can be identified, e.g. in an environment with essentially no human habitation, it would nevertheless be important to assess doses to a hypothetical critical group in order to demonstrate conformity with the principle of protecting the environment (see para. 1.7). For example, for discharges to the atmosphere, one might assume that the hypothetical critical group is located at the boundary of the facility, or at a distance corresponding to the highest predicted concentrations of the radionuclides in air. For aquatic discharges, one might assume that all water usage and/or exposure occurs at the point of discharge. However, exposure pathways, food consumption rates and other characteristics assumed should be typical for the type of environment under consideration.

3.35. The results from this assessment should be compared with the appropriate dose constraint. Options for the management of radioactive waste that give rise to doses higher than the dose constraint should be rejected and alternative options should be considered.

SETTING A DISCHARGE AUTHORIZATION

3.36. Authorized discharge limits are set by the regulatory body. The limits shall satisfy the requirements for the optimization of protection and the condition that doses to the critical group shall not exceed the appropriate dose constraints (Ref. [3], paras 2.24–2.26). They should also reflect the requirements of a well designed and well managed practice and should provide a margin for operational flexibility and variability. In order to satisfy these requirements, the numerical values of the authorized discharge limits should be close to, but generally higher than, the discharge rates and quantities resulting from the calculations for optimization of protection to allow margin for operational flexibility, although they should never exceed the discharge level corresponding to the dose constraint (see also Fig. 3 in the Appendix).

3.37. 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. They can be presented in a number of ways. The discharge limits can refer to the complete spectrum of radionuclides to be discharged, or nuclides can be combined in appropriate groups such as, for example, noble gases or halogens. Limits for specific nuclides might be adopted if the radionuclides are radiologically significant, if they are major contributors to the discharges or if they serve as indicators of plant performance. They should be selected in such a way as to allow a normal degree of flexibility in the operation of the source or facility, i.e. values chosen for limits will be higher than the values resulting from any studies of the optimization of protection.

However, the values selected should not exceed those corresponding to the dose constraints; i.e. they should satisfy the following condition:

$$\sum_i \sum_k (f_{ik})_{\text{model}} \cdot Q^*_{ik} \leq \frac{E_{\text{constraint}}}{\Gamma} \quad (1)$$

where

$(f_{ik})_{\text{model}}$ is the maximum future annual dose to the critical group, calculated with a particular model and for the discharge of radionuclide or radionuclide group i by discharge route k per becquerel.

Q^*_{ik} is the discharge limit, in becquerels, on the annual release of radionuclide or radionuclide group i by discharge route k.

$E_{\text{constraint}}$ is the dose constraint for the source under control.

Γ is a safety factor to take account of the uncertainty in the model used to calculate doses so as to provide sufficient confidence that the source related dose constraint will not be exceeded.

3.38. The value used for the safety factor Γ will depend on the model and data used to assess doses, and on any margins to account for uncertainty that have already been incorporated into the setting of the dose constraint itself. For site specific studies, values for Γ can be selected with due consideration, as appropriate, of evaluations of the reliability of model predictions, for which guidance is given in Ref. [15].

3.39. The characteristics of potential critical groups, corresponding to different discharge routes, may not be the same. If they are not the same, it is unlikely that the real or actual critical group would receive doses as high as those predicted by summing the potential critical group doses from all discharge routes. Nevertheless, in the absence of any site specific information about the locations and characteristics of the critical groups, a cautious approach, for the purposes of establishing a discharge authorization, would be to sum the potential critical group doses for all pathways and radionuclides released.

3.40. While discharge limits can be placed on significant individual radionuclides, it may also be convenient in some circumstances to express them as limits on radionuclide groups, such as noble gases, radioiodines, gross alpha activity of discharge and/or gross beta activity of discharge, and so on. The dose assessments, i.e. the values for f_{ik} in Eq. (1), would then be based on the most critical radionuclide in that particular grouping.

3.41. Some countries have placed dose constraints on effluent releases that are source specific (e.g. for a given site or facility) and specific to discharge mode (e.g. for airborne or liquid discharges), for ease of application. The condition expressed in Eq. (1) can be modified to accommodate this approach so that parallel conditions should be fulfilled for each source and discharge mode. The authorized limits that are specific to radionuclides and to discharge modes that meet these conditions will then be selected.

3.42. Discharge authorizations are normally set in terms of annual limits. While these are the primary limits, shorter term levels can be set in order to: (i) trigger investigations; and (ii) ensure that the procedure used and the associated conditions and assumptions used to estimate doses remain valid, e.g. to prevent significantly higher doses being received owing to higher than normal discharges in conditions of poor dispersal in the environment. As an illustration, these levels could be set at 50% of the annual limit for a calendar quarter, 20% of the annual limit for a calendar month, or 10% of the annual limit for a week, as considered appropriate, with account taken of the nature and operation of the source. Although this should not be seen as a breach of the statutory discharge authorization, the operator should be required to notify the regulatory body if the shorter term levels are exceeded, to state the reasons for their being exceeded, and to propose mitigatory measures. This information will also be useful in determining whether the control of discharges is optimal.

3.43. 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. A new source for which experience is limited should be reviewed by the regulatory body at least once in the first three years. For licensed sources continuing in use, review should, for example, be at least once every five years. Registered sources with only low levels of discharge should be reviewed regularly but at longer intervals. At any event, a review of the authorization 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.

3.44. In order to demonstrate that discharges are in compliance with the limits, effluent monitoring may be necessary. Similarly, in order to check the assumptions used to evaluate critical group doses, environmental monitoring may also be needed. Environmental monitoring also provides an additional means, besides effluent monitoring, of checking for unexpected releases. The requirements for monitoring should be specified in the discharge authorization.

3.45. The manner in which discharge limits are expressed and the need for monitoring depend to some extent on the assessed level of critical group dose. The recommended approach is described in the following and is summarized in Table I.

TABLE I. SUMMARY GUIDANCE ON REGULATORY REQUIREMENTS IN RELATION TO PREDICTED DOSES TO THE CRITICAL GROUP *(see para. 3.45)*

	Assessed future maximum annual dose to the critical group		
	≤10 μSv		>10 μSv
	A	B	C
Regulatory requirements in relation to discharges	EXEMPTION OR NOTIFICATION	REGISTRATION	LICENCE
Recommended conditions	— Source inherently safe — No requirements on effluent or environmental monitoring — Practice to be kept under periodic review	— Source not inherently safe — Discharge limits required — Effluent monitoring required — Practice to be kept under review — Recording of discharges required	Formal authorization with specific conditions attached to the authorization, on any or all of the following: — Discharge limits — Effluent monitoring — Environmental monitoring — Effluent and environmental monitoring records — Reporting of monitoring to regulatory body
Example facilities	— Research laboratories using radio-immunoassay techniques — Hospitals using xenon testing kits	— Small hospitals and research and development facilities using limited amounts of radioisotopes	— Nuclear reactors — Reprocessing facilities — Radioisotope production facilities

(a) If the maximum future assessed annual dose to the critical group is less than or equal to 10 μSv, the regulatory body may investigate whether the source may be exempted from some regulatory requirements or whether notification is appropriate. Guidance on this matter is given in Section 2 and in the BSS [3]. For exemption, the source should be inherently safe and the practice of which it forms a part should be justified. If the discharge is exempted from regulatory control, then neither effluent monitoring nor environmental monitoring is required. Simple checks could be made on discharge levels, for example, from estimates of activity balance. These conditions may apply at facilities such as research laboratories using radioimmunoassay techniques and hospitals employing xenon testing kits.

(b) If the maximum future assessed annual dose to the critical group is less than or equal to 10 μSv, but if the source is not considered inherently safe, the regulatory body should issue a discharge authorization specifying discharge limits and a requirement for effluent monitoring as a minimum. A record of the discharges made should be maintained. Examples of facilities for which these conditions may apply are small hospitals and research and development facilities using limited amounts of radionuclides for diagnostic testing or tracer studies, or facilities where containment is very strict (very low discharges) but accidental discharges are possible. Sources falling into this category may be candidates for registration rather than licensing.

(c) If the maximum future assessed annual dose to the critical group is in excess of 10 μSv, the discharge authorization should specify discharge limits and include requirements both to monitor the discharges and, where appropriate, to monitor radionuclide levels in the environment. The objective of the environmental monitoring programme is to ensure that the regulatory requirements for the discharge of radioactive substances to the environment are satisfied and that the assumptions about conditions made in deriving the authorized discharge limits remain valid. The degree of environmental monitoring required is linked to the assessed critical group dose. For annual doses less than about 100 μSv, a simple monitoring check of the critical pathways may be all that is necessary.[9] In the event of assessed doses being higher than 100 μSv per year, a more comprehensive environmental monitoring programme is necessary. This programme should cover all relevant exposure pathways and be so designed as to allow a comprehensive evaluation of critical group doses. The scale and/or scope of the effluent monitoring and environmental monitoring programme and the measurement methods used should be agreed upon by the regulatory body. The

[9] In some countries the annual dose constraint for nuclear power reactors is of the same order of magnitude. In these cases, the conditions set by the regulatory bodies for environmental monitoring may be more stringent.

registrant/licensee should keep appropriate records of the monitoring programmes and report to the regulatory body at approved intervals. Discharge authorizations for this category of sources are likely to include limits on individual radionuclides. Furthermore, short term limits may also be required, as described earlier. Facilities which fall into this category include all large scale nuclear facilities, such as nuclear reactors, reprocessing plants and radioisotope production facilities. Sources falling into this category are likely to be candidates for licensing rather than registration.

3.46. In setting authorized discharge limits, the regulatory body should take account of the Waste Safety Fundamentals [1]. The following two principles are particularly relevant in the context of discharges to the environment:

— Principle 3, dealing with transboundary effects, states that "Radioactive waste shall be managed in such a way as to assure that possible effects on human health and the environment beyond national borders will be taken into account." Moreover, as a basic principle, deriving from the Safety Fundamentals and the BSS, policies and criteria for radiation protection of populations outside national borders from discharge of radioactive substances should be at least as stringent as those for the population within the country of discharge (see also para. 3.24). Application of this principle can be furthered by exchange of information or by making appropriate arrangements with neighbouring or affected countries [16].
— Principle 4 states that "Radioactive waste shall be managed in such a way that predicted impacts on the health of future generations will not be greater than relevant levels of impact that are acceptable today." This could be taken into account, as it is in this Safety Guide, in setting an appropriate dose constraint and by ensuring that the buildup of long lived radionuclides in the environment is given due consideration in the dose assessment.

In the few instances of large nuclear facilities discharging long lived radionuclides that can reach a worldwide distribution, consideration should be given to the establishment of appropriate effluent control measures to limit global environmental pollution.

4. RESPONSIBILITIES IN OPERATION

4.1. Registrants and licensees should, during the operational period of sources under their responsibility, keep all radioactive discharges as far below authorized limits as is reasonably achievable and report promptly to the regulatory body any releases

exceeding any reporting levels or authorized discharge limits in accordance with criteria specified in the discharge authorization issued by the regulatory body [3].

4.2. Registrants and licensees should review discharges and their associated control measures at regular intervals in the light of operating experience. Furthermore, the implications of any changes in exposure pathways and of any changes in the composition of critical groups that would affect calculated doses should also be kept under review and taken into account whenever the discharge authorization is reviewed.

4.3. In general, discharges from sources subject to registration will be lower than those from licensed sources, and the requirements for monitoring and reporting of radionuclide discharges may be correspondingly less stringent, as described in Section 3.

4.4. Registrants and licensees should, where appropriate, establish and carry out monitoring programmes for effluents and environmental radiation. The purpose of these programmes is to ensure that the requirements established by the regulatory body in granting a discharge authorization are satisfied, and in particular that the assumptions about conditions in deriving the authorized discharge limits remain valid. The monitoring programme should enable exposures to critical groups to be assessed with the appropriate degree of confidence. The scale and scope of these monitoring programmes should be, as a minimum, in accordance with the guidelines set out in Section 3.

QUALITY ASSURANCE

4.5. Appropriate quality assurance programmes should be established whenever effluent or environmental monitoring programmes are required.

4.6. Measures to satisfy the following specific conditions should be incorporated into the quality assurance programmes:

— Requirements relating to effluent and environmental monitoring and to sampling representativity should be properly implemented,
— The environmental media and the associated sampling frequency should be appropriate,
— Procedures for the calibration and performance testing of measurement equipment should be adequate,

— A programme of intercomparison of measurements should be in place,
— Measurements should be traceable to international standards,
— Analytical laboratories should be appropriately accredited,
— The record keeping system should be adequate,
— The reporting procedure should be in compliance with that agreed with the regulatory body.

NON-COMPLIANCE WITH AUTHORIZED DISCHARGE LIMITS

4.7. This Safety Guide provides guidelines for the setting of discharge limits for the normal operation of sources, which includes anticipated fluctuations as discussed in Section 3. However, unanticipated situations may arise that necessitate the release of effluents in excess of the limits specified in the authorization. In such a case, the licensee or registrant may make a special application providing details of the circumstances leading to the situation and also providing a justification for the need for the special release of effluents. The regulatory body may, upon such a request, grant a special authorization for the discharge provided that the resulting maximum future critical group dose does not exceed 5 mSv in one year and the average annual dose in a five year period is limited to 1 mSv, including doses from all other controlled sources.

4.8. In other situations where authorized discharge limits have been exceeded, the registrant or licensee 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) 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.

4.9. The communication of a breach of the authorized discharge limits should be prompt and it should be immediate whenever an exposure emergency has developed or is developing. Failure to take corrective or preventive actions within a reasonable time in accordance with national regulations should be grounds for modifying, suspending or withdrawing any authorization that was granted by the regulatory body. Non-compliance with authorized discharge limits or other relevant regulatory requirements concerning control of radioactive discharges is subject to the provisions laid down in relevant national legislation or by the regulatory body.

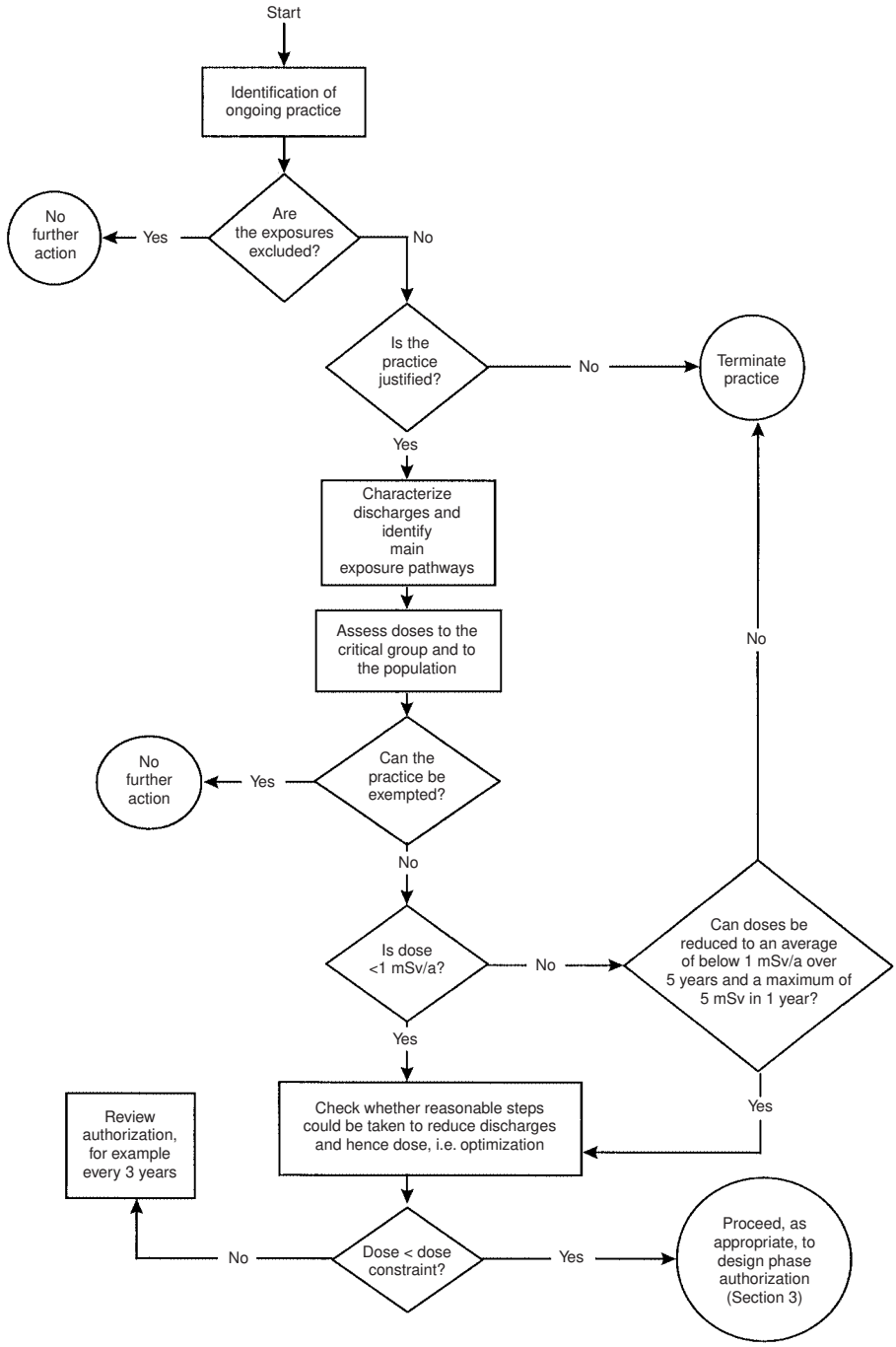

FIG. 2. Procedure for setting a discharge authorization for existing sources that are not operating within the conditions set according to Sections 3 and 4.

5. EXISTING PRACTICES

5.1. Sections 3 and 4 cover the setting of, and operations under, a discharge authorization for a new or proposed facility. However, the regulatory body may identify existing practices or sources that are already releasing radionuclides and which are not operating within requirements, i.e. where authorized discharge limits and associated conditions have not been set as specified in Sections 3 and 4 or have not been set to at least equivalent requirements. The objective here is not necessarily to require the practice to cease but to implement the requirements for discharge control in a structured manner. An approach for implementation is illustrated in Fig. 2.

5.2. The regulatory body should, firstly, establish whether the specification of authorized discharge limits is required as described in Section 3; that is, account should be taken of whether the exposures are excluded, whether the practice is justified and whether the practice or source can be exempted. As mentioned earlier, justification of a practice is generally not the responsibility solely of the radiation protection body.

5.3. If authorized discharge limits are required, discharges from the source should be adequately characterized, a dose constraint should be established and an appropriate dose calculation should be undertaken, as described in Section 3. If the assessed annual maximum doses to the critical group are below the dose constraint, the source can continue in operation and the regulatory body should establish authorized discharge limits as described in Section 3.

5.4. If the assessed maximum annual doses to the critical group are in excess of the dose constraint, these assessed doses should be compared with the annual dose limit of 1 mSv or an appropriate fraction of the annual dose limit if there are other sources contributing to the critical group dose. If the assessed annual dose is greater than the dose constraint but below 1 mSv, a discharge authorization should be set as described in Section 3. In circumstances where the assessed annual doses are greater than 1 mSv, the regulatory body should set 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 one year. In circumstances in which this cannot be achieved, closing down the discharge practice should be considered, with account taken of all other relevant factors. In both cases authorizations should be reviewed at frequent intervals, say every three years, and should focus on cost effective ways of reducing discharges, with regard paid to comparable practices in other places. The ultimate objective is to reduce the doses to below the dose constraint that would have applied had it been a new source.

5.5. There may be situations in which the dose to the critical group is in excess of dose limits owing to either 'pre-existing' contamination or current contributions from more than one source. Pre-existing contamination can be due to past accidents or past discharges from the source which were authorized on the basis of previous standards. These contributions should not be considered in deriving current discharge limits but should be addressed within the scope of an intervention framework. If current contributions from different sources result in doses in excess of dose limits, the regulatory body should seek agreement with the relevant organization/company operating the facility in order to ensure that dose limits are complied with. If such an agreement is not reached, the regulatory body should establish and enforce appropriate discharge limits.

Appendix

GENERIC UPPER VALUE FOR A DOSE CONSTRAINT FOR MEMBERS OF THE PUBLIC

A.1. In setting a dose constraint, the following factors should be taken into account:

(a) Dose contributions from other sources and practices, including realistically assessed possible future sources and practices on a regional and global scale;
(b) Reasonably foreseeable changes in any condition that could affect public exposure, such as changes in the characteristics and operation of the source, changes in exposure pathways, changes in the habits or distribution of the population, modification of critical groups, or changes in environmental dispersion conditions; and
(c) Any uncertainties including conservatisms associated with the assessment of exposures, especially in potential contributions to the exposures if the source and the critical group are separated in distance or time.

Additionally, consideration should be given to:

(d) The result of any generic optimization of protection for the source, practice or task being considered; and/or
(e) The experience of well managed operation of practices or sources of the same kind.

A.2. One of the most important points to take into consideration is the possibility of similar facilities being built on the same site in the future; for example, once one reactor has been built on a particular site others may be built to form a reactor park. Similar considerations may apply to other facilities; for example research laboratories or hospitals could be expanded at one location.

A.3. 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. Table II summarizes the values used in some Member States. There is a relatively narrow range of annual doses of between 100 and 300 μSv; however, these values are all for nuclear fuel cycle facilities (including reactors).

TABLE II. DOSE CONSTRAINTS AND THE SOURCES TO WHICH THEY APPLY FOR SEVERAL MEMBER STATES

Country	Dose constraint ($mSv \cdot a^{-1}$)	Source
Argentina	0.3	Nuclear fuel cycle facilities
Belgium	0.25	Nuclear reactors
China	0.25	Nuclear power plants
Italy	0.1	Pressurized water reactors
Luxembourg	0.3	Nuclear fuel cycle facilities
Netherlands	0.3	Nuclear fuel cycle facilities
Spain	0.3	Nuclear fuel cycle facilities
Sweden	0.1	Nuclear power reactors
Ukraine	0.08	Nuclear power reactors
	0.2	Nuclear fuel cycle facilities
United Kingdom	0.3	Nuclear fuel cycle facilities
United States of America	0.25	Nuclear fuel cycle facilities

A.4. Because it is not easy to arrive at generally applicable constraints for individual sources or practices, establishing a single generic dose constraint is not reasonable. However, it may be possible to estimate a generic upper value for a dose constraint by a procedure that takes into account maximum per capita estimates of global and regional annual doses, the buildup of radionuclides in the environment over a specified period of time and the dose contributions from possible exempt sources. Subtracting these contributions from the annual dose limit of 1 mSv results in dose values that are in a range in which the generic upper value of dose constraint can be chosen. This procedure is illustrated in Fig. 3.

A.5. An estimate of the population radiation dose from global, regional and other sources can be derived from data in the 1993 UNSCEAR report [12]. Essentially the only global contributions arise from ^{3}H, ^{14}C, ^{85}Kr and ^{129}I released from past atmospheric testing of nuclear weapons and nuclear power production and from ^{222}Rn emanating from tailings from uranium mines and mills. Some radioactivity also arises from the discharge of long lived radionuclides during radiopharmaceutical production and use. It might be assumed that nuclear power is used for, say, 500 years and that all the spent fuel for 500 years is completely reprocessed (compared with about 4% at present). The maximum future annual per caput dose from global nuclides can be obtained from the 500 year truncated collective effective doses. The only nuclides contributing significantly to collective effective dose are ^{14}C and ^{222}Rn.

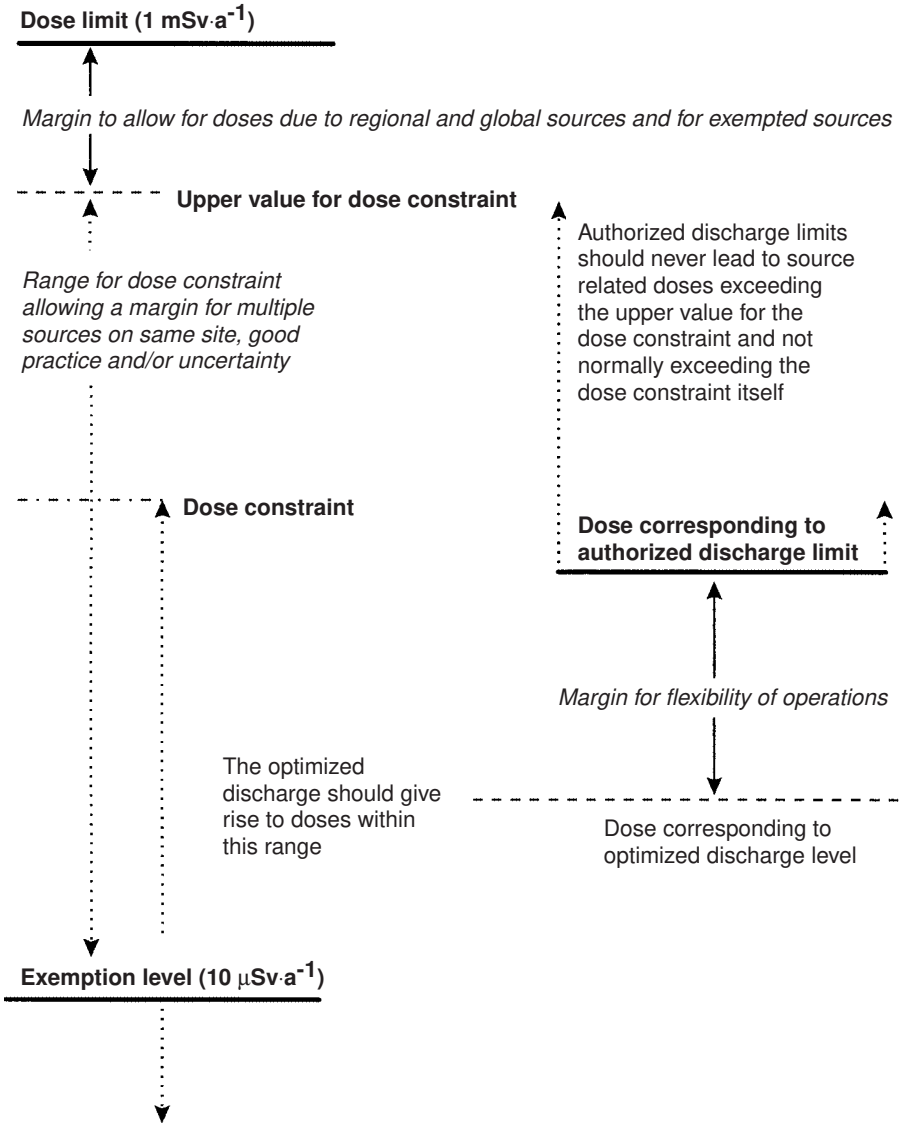

FIG. 3. Considerations in setting a source related dose constraint and an authorized discharge limit.

A.6. The 500 year truncated collective effective dose from ^{14}C and ^{222}Rn under these circumstances, derived from the 1993 UNSCEAR report [12], is 12 man Sv $(GW{\cdot}a)^{-1}$. This can be shown to be equivalent to the maximum future annual collective dose from 500 years of operation normalized for energy production. UNSCEAR assumes

a nuclear power programme corresponding to an installed capacity of 1 kW per caput, i.e. 10^4 GW in 500 years' time, assuming a global population of 10^{10} and a constant level of technology. The maximum future annual per caput committed dose from the 500 years is then approximately 12 μSv.

A.7. Estimates of regional doses are also derived from the 1993 report of UNSCEAR [12], which gives a maximum future annual collective dose of around 10 man Sv $(GW{\cdot}a)^{-1}$ if all fuel is reprocessed, and an assumed regional population of some 250 million people. With an installed capacity of perhaps some 2000 GW·a per year in 500 years' time produced by the region's nuclear industry, this implies a maximum future annual per caput committed dose of about 80 μSv in some 500 years' time. The dominant contribution is from aquatic releases during reprocessing, and thus the regional component is sensitive to the assumptions about the percentage of the fuel reprocessed.

A.8. The contribution from possible exempt sources should also be included. Exemption may be granted on the basis of an annual individual dose of 10 μSv or less from a given source [3]. As such, a contribution from several (of the order of ten) exempted sources could be assumed.

A.9. As a result, approximately 200 μSv in a year per caput is a maximum future value estimated for the total of the contributions from global, regional and exempt sources. The remainder, about 800 μSv committed in a year, can be considered as an upper bound for a dose constraint. However, on the basis of a review of the dose constraints generally in use today in various countries (Table II), 300 μSv committed in a year is suggested as a default value for a source related dose constraint. This default value takes account of the possibility that other facilities discharging radionuclides may be built nearby in the future, e.g. the development of a reactor park, and that other local sources may contribute to the dose committed to a member of the public. The indications resulting from the above assessment procedure find confirmation in a recent ICRP Publication [17] which states that "to allow for exposures to multiple sources, the maximum value of the constraint used in optimization of protection for a single source should be less than 1 mSv in a year. A value of no more than about 0.3 mSv in a year would be appropriate." In some special situations, however, there may be circumstances (e.g. for a specific practice that cannot have multiple sources contributing to the public dose, or in extremely remote locations, or where the global and regional components are evaluated more accurately) that could allow for constraints to be higher than 300 μSv annual dose, but less than 1 mSv in a year.

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Annex

BASIC RADIOLOGICAL PROTECTION CONCEPTS RELEVANT TO THIS SAFETY GUIDE

A–1. Exposure to radiation at high doses can cause acute syndromes that are clinically expressed in exposed individuals within a short period of time after exposure. Such effects are called *deterministic* effects because they are certain to occur if the dose exceeds a threshold level and their severity increases with the dose. At lower doses, defined by the International Commission on Radiological Protection (ICRP) as an absorbed dose of less than 0.2 Gy, radiation exposure can induce malignancies in exposed individuals and could also have detrimental hereditary effects in their offspring. These effects are called *stochastic* effects because of their random nature. They are characterized by their probability of occurrence being a function of dose, over a large range of doses, without a dose threshold, while their severity is independent of dose.

A–2. For radiation protection purposes, it is assumed that there is a *proportionality* between dose and the probability of a stochastic effect within the range of doses encountered in radiation protection. A consequence of this assumption is that doses are additive in the sense that equal dose increments give rise to equal increments of the probability of a deleterious effect, which are independent of the previously accumulated dose.

A–3. Risk is defined by the ICRP (Ref. [A–1]) and the BSS (Ref. [A–2]) as a multi-attribute quantity expressing a probability of harmful consequences associated with a radiation exposure. The parameters which define the risk include such quantities as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences. For the purposes of this report, the word *risk* is used to mean the probability that a given individual will incur a severe stochastic effect as a result of a radiation dose. Under the above mentioned assumption of proportionality, the risk to an individual is proportional to the effective dose to that individual. The effective dose is based on the concept that, at a given level of protection, the risk should be equal whether the whole body is irradiated uniformly or whether there is non-uniform or partial irradiation. The effective dose, E, is defined as:

$$E = \sum_T w_T H_T \qquad \text{(A–1)}$$

where H_T is the mean equivalent dose in each tissue T and W_T is the corresponding tissue weighting factor proposed by the ICRP for that tissue T. The unit of effective dose is the sievert (Sv).

A–4. The ICRP has introduced the concept of *committed dose*, which is defined as the sum of doses that would be received by an individual during a given time period following the intake of a radioactive substance. When this integration time is not specified, it is taken to be 50 years for adults and up to 70 years for children. This concept is needed in order to apply the basic objective for radiation protection of limiting the lifetime risk committed in a year of operation of a practice, rather than limiting the dose delivered in that year.

A–5. The quantity that reflects the risk committed in any year is the sum of the effective dose from external irradiation in that year and the committed effective dose from intakes in the same year. The term *annual dose* in this Safety Guide includes both quantities. More generally, the term dose, unless otherwise qualified, refers to the sum of the effective doses to an individual accumulated in a given period of time from external irradiation and the committed effective doses from intakes in the same period.

A–6. The dosimetric quantities referred to above all relate to the exposure of an individual. The total impact of the radiation exposure due to a given practice or source depends on the number of individuals exposed and the doses they receive. The *collective dose,* defined as the summation

$$S = \sum_i E_i N_i$$

of the products of the mean doses E_i in the various groups of exposed people and the numbers N_i of individuals in each group i, may be used to characterize the total radiation impact of the practice or source. The unit of collective dose is the man-sievert (man Sv).

A–7. An important concept to be used in the limitation of radioactive discharges is the concept of *dose commitment*. If a practice continues over a long period of time, long lived radionuclides released to the environment cause annual exposures which initially increase with time and generally reach a maximum after a certain number of years. The dose commitment is the infinite time integral of the average (per caput) dose rate $\dot{E}(t)$ caused by the practice:

$$E_c = \int_0^\infty \dot{E}(t) \cdot dt \qquad \text{(A–2)}$$

Analogously, a *collective dose commitment* can be defined as a measure of the total exposure of a population group from a unit of operation of the practice. This is the infinite time integral of the collective dose rate $\dot{S}$ caused by that practice:

$$S_c = \int_0^{\infty} \dot{S}(t) \cdot dt \qquad \text{(A–3)}$$

A–8. It can be demonstrated (Ref. [A–3]) that, if the integration period is chosen to be equal to the expected duration T of the practice and if the practice can be assumed to continue at a constant rate, then the *incomplete* (or *truncated*) dose commitment per unit of practice (e.g. one year of operation) is equal to the maximum per caput annual dose in the future:

$$E_{\max} = \int_0^{T} \dot{E}(t) \cdot dt \qquad \text{(A–4)}$$

Similarly, the *incomplete* (or *truncated*) collective dose commitment per unit of practice (e.g. one year of operation) integrated over the expected duration T of the practice is equal to the maximum annual collective dose in the future from that practice:

$$S_{\max} = \int_0^{T} \dot{S}(t) \cdot dt \qquad \text{(A–5)}$$

A–9. These concepts of dose commitment and incomplete dose commitment are particularly important for the limitation of radioactive discharges from practices or sources continuing over extended periods and releasing long lived radionuclides that remain in the environment for a long time. In these cases, the discharge limits should be aimed at limiting the annual dose commitment per year of practice operation — which coincides with the value of the maximum annual dose in the future — rather than the dose delivered in any particular year.

A–10. Radioactive substances released to the environment are sources of radiation exposure to humans. Such releases may occur from the operation of a number of practices, which are defined as those human activities that add radiation doses to those which people normally incur owing to background radiation, or that increase the likelihood of their incurring exposure.

A–11. The BSS (Ref. [A–2]) establish requirements for protection against risks associated with exposure to radiation and for the safety of radiation sources that may deliver such exposure. In particular, they identify requirements that should be imposed by the regulatory body *before* discharges of radionuclides to the environment are initiated and during subsequent discharge operations.

A–12. "The principles of radiation protection and safety on which the (Basic Safety) Standards are based are those developed by the ICRP…" (see Ref. [A–4] and Ref. [A–5], Preamble). The principles can be summarized as follows: that a practice that entails or could entail exposure to radiation be adopted only if it yields sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes or could cause (principle of justification of a practice); that individual doses due to the combination of exposures from all relevant practices not exceed specified dose limits (principle of individual dose limitation); that radiation sources and installations be provided with the best available protection under the prevailing circumstances, so that the magnitudes of exposures and the number of individuals exposed be kept as low as reasonably achievable, economic and social factors being taken into account, and so that the doses they deliver be constrained (principle of optimization of protection).

A–13. The principle of justification applies to the practice as a whole and not solely to individual parts of the practice such as radionuclide discharges arising from it, although any consequent exposures would be taken into account in the justification process. Decisions on justification of a practice go beyond radiological protection and involve consideration of the benefit of the practice. Hence they are not usually the responsibility solely of the regulatory body.

A–14. *Dose limits* (Table A–I) apply to the whole *of exposures attributable to practices*. It follows that the annual dose from any one source within a practice should be such that, taken together with annual dose contributions from other sources subject to control, the relevant dose limit not be exceeded, either now or in the future.

A–15. For any given practice or source discharging radioactive effluents to the environment, the above condition applies to the average annual individual dose to members of the *critical group* for that practice or source. A critical group is a group that is representative of those individuals who are expected to receive the highest dose from the source subject to control and is defined so that it is reasonably homogeneous with respect to factors that affect the dose received. The critical group concept is adopted because the average behaviour of a group of people, rather than the behaviour of any one individual, is more likely to reflect behaviour that will occur on a continuing basis. The regulatory body should note that the most exposed individuals may

be located beyond national borders and this should be taken into account in setting discharge limits. In estimating critical group doses, account should be taken of any possible buildup of radioactive material in the environment due to present and future discharges.

A–16. Individuals are exposed via *exposure pathways*, which are routes by which radioactive material can reach or irradiate humans. Examples of exposure pathways are the consumption of fish containing radionuclides from discharges to rivers or seas and external irradiation from gamma emitting radionuclides discharged to the atmosphere. The importance of a particular exposure pathway depends upon the physical and chemical properties of the radionuclide concerned as well as the particular features of the environment and habits of the population exposed (see Ref. [A–6]).

A–17. The dose limits are related to individuals irrespective of the source of exposure, and apply, as mentioned, to the total dose from all relevant sources affecting a given population group. Therefore, they cannot, in principle, be applied directly to limit the dose contribution from a particular practice or source if the critical group for that practice or source is liable to be exposed to other sources. As a consequence, the limitation of radioactive discharges from a practice or source should result in a source specific limitation of the dose to individuals of the critical group.

A–18. According to the recommendations of the ICRP (Ref. [A–1]) and in the BSS (Ref. [A–2]), optimization of radiation protection should be constrained by restrictions on the doses to individuals from the practice or source under consideration. For this purpose, *a dose constraint* is to be set before the optimization of protection in the

TABLE A–I. DOSE LIMITS FOR MEMBERS OF THE PUBLIC (Ref. [A–2])

Dose	Level
Effective dose	1 mSv in a year; in special circumstances up to 5 mSv in a single year provided that the average dose over five consecutive years does not exceed 1 mSv per year
Equivalent dose to the lens of the eye	15 mSv in a year
Equivalent dose to the skin	50 mSv in a year, averaged over 1 cm^2 of the most highly irradiated area of the skin

design and operation of the radioactive discharge system. Its function is to set a ceiling on the values of individual doses that could result from the planned operation of the practice or source under consideration, and in particular from its radioactive discharges. In other words, the effluent treatment and discharge option which is chosen as a result of the optimization process should satisfy the condition that the corresponding doses to the individuals of the critical group do not exceed the dose constraint.

A–19. The use of dose constraints is *prospective* because it only applies to the planning of protection in the design and operation of the radioactive discharge system. *Dose constraints are not to be seen as limits for operational purposes.* Rather, when the optimization of protection under constraint is completed, the constraints cease to be operationally relevant and authorized limits of discharge (in terms of activity per unit time), corresponding to individual doses not exceeding the constraints, are to be chosen as a result of optimization and used as the actual limits for operation (Ref. [A–7]).

A–20. Although the dose constraint is expressed in terms of individual dose, it is a source related quantity that refers to the discharge system to which the optimization process is applied. The exposure to which the dose constraint applies is normally expressed in terms of the prospective annual dose to any critical group, summed over all exposure pathways, arising from the predicted operation of the radioactive discharge system.

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