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A general framework for prospective radiological environmental impact assessment and protection of the public

DRAFT SAFETY GUIDE **DS427**

FOREWORD

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CONTENTS

1. INTRODUCTION

1.1. In 2011, the IAEA published the interim version of the Safety Requirements: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3 (GSR Part 3) [1]. These standards superseded the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources issued in 1996. GRS Part 3 was reissued in 2014 [1] with the cosponsoring of the European Commission (EC), the Food and Agriculture Organization of the United Nations (FAO), the IAEA, the International Labour Organization (ILO), the OECD Nuclear Energy Agency (OECD/NEA), the Pan American Health Organization (PAHO), the United Nations Environment Programme (UNEP) and the World Health Organization (WHO). GSR Part 3 [1] is based on the IAEA's Fundamental Safety Principles [2] and the recommendations of the International Commission on Radiological Protection (ICRP) [3].

1.2. The system of protection and safety aims to assess, manage and control exposure to radiation [1]. The protection of the public is based on the principles of justification, dose limitation and optimization, which were specified by the ICRP [3] and are incorporated in the IAEA Safety Standards [1, 2].

1.3. As part of the (regulatory) authorization process, GSR Part 3 [1] identifies the requirement for a prospective assessment of the radiological environmental impacts due to releases of radionuclides from facilities and activities[1]. This prospective assessment includes the consideration of expected exposures (e.g. due to releases during normal operation) and potential exposures (e.g. exposures due to conceivable[2] accidents).

1.4. The present Safety Guide interprets and elaborates on the requirements in GSR Part 3 for performing such assessments for certain facilities and activities and, in particular, on Requirement 7 for notification and authorization, which states that "Any person or organization applying for authorization: […] shall, as required by the regulatory body, have an appropriate prospective assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity" [1].

1.5. In the framework of international legal instruments or national laws and regulations, States may also require that, for some activities or facilities, a governmental decision-making process, including a comprehensive initial assessment of the possible significant effects on the environment, is carried out at an early stage. In this case, the radiological environmental impact assessment is generally part of a broader impact assessment, which is generally referred to as an 'environmental impact assessment' (known by its acronym EIA and defined later). EIA covers not only environmental but biophysical, social, economic and other relevant effects of development-proposals prior to major decisions being taken. Within that framework, the results of the radiological environmental impact assessment presented in this

[1] Facilities and activities are defined in the IAEA Fundamental Safety Principles and the Safety Glossary [2, 4]. It is a general term encompassing all nuclear facilities and uses of all sources of ionizing radiation. The present guidance is pertinent to certain facilities and activities which are described under Scope.

[2] In the context of the Safety Guide, the term 'conceivable' means that the incidents to be considered are the result of a safety analysis, which includes the definition not only of the characteristic of the incident but its probability.

Safety Guide may be used to inform judgements on the acceptability of the risk of such impacts, as defined by the requirements and recommendations in the IAEA safety standards.

1.6. This Safety Guide is related to other IAEA Safety Standards Series: These are the Safety Requirements for safety assessment of activities and facilities [5] and the Safety Guides for protection of the public and protection of the environment against radiation exposure [6], on criteria for use on emergency preparedness and response [7] and on regulatory control of radioactive releases to the environment [8].

1.7. This Safety Guide provides a general framework that is consistent with and can be applied as a complement to other Safety Guides providing frameworks for safety assessments for activities and facilities. In those Safety Guides, the concept of radiological environmental impact assessment, as part of the safety assessment, is included, but discussed with less level of details; for example, in the frameworks of safety assessment for predisposal management of radioactive waste [9] and safety assessment for the decommissioning of facilities using radioactive material [10].

1.8. This Safety Guide is also related to other technical documents published by IAEA, such as the Safety Report on methods and models to assess the impact of releases to the environment [11, 12] and the Technical Report(s) relevant to environmental transfer parameters [13–15].

OBJECTIVE

1.9. This Safety Guide provides recommendations and guidance on a general framework for performing prospective radiological impact assessments for facilities and activities —as identified under Scope—, to estimate and control, using criteria, the radiological effects on the public and on the environment. This radiological assessment is intended for planned exposure situations as part of the (regulatory) authorization process and, when applicable, the governmental decision-making process for facilities and activities. The situations covered include expected exposures and potential exposures (this is explained in more details in Section 2).

1.10. This Safety Guide provides general guidance and recommendations about the contents of such radiological environmental impact assessments, their use and the procedures for their implementation, as an aid to national regulatory bodies, persons or organizations and to other interested parties[3] applying for an authorization or being responsible for the operation of facilities and activities. It is recognized and discussed in this guidance that, for some aspects of the assessments, different States may have different approaches. This is due to the complexity and diversity of the options for management of environmental issues, which will

[3] The term interested parties is used in the IAEA safety standards to mean, in a broad sense, a person or group having an interest in the performance of an organization. Interested parties have typically included the following: customers, owners, operators, employees, suppliers, partners, trade unions; the regulated industry or professionals; scientific bodies; governmental agencies or regulatory bodies (national, regional and local) whose responsibilities may cover nuclear energy; the media; members of the public (individuals, community groups and interest groups); and other States, especially neighbouring States that have entered into agreements providing for an exchange of information concerning possible transboundary impacts, or States involved in the export or import of certain technologies or materials.

depend on the characteristics of the facilities and activities, the environmental scenarios and the national circumstances.

SCOPE

1.11. The Safety Guide covers those facilities and activities for which, accordingly to their characteristics and to national or international applicable regulations, a radiological environmental impact assessment is mandatory (for guidance on how to determine the need and complexity of a radiological environmental impact assessment see Section 4).

1.12. This Safety Guide is applicable to evaluate prospectively radiation exposures and risk of radiation exposures due to radioactive releases to the environment —and, when relevant, direct external radiation—, from facilities and activities which are located at or projected for a specific or generic site, and from which public and the environment may be exposed[4].

1.13. The radiation exposures considered include those which are expected to occur as a result of normal operation (i.e. due to the authorized discharges) and also those which can be conceived, by mean of a safety analysis[5], as a result of an event or a sequence of events that might be an accident[6] (i.e. potential exposures).

1.14. It is beyond the scope of this Safety Guide to provide recommendations and guidance on equivalent prospective assessments of exposures resulting from the disposal of radioactive waste, the transport of radioactive material and the use of mobile radioactive sources. These types of facilities and activities have very specific aspects related to, for example, the risk of long-term delayed releases to geosphere (for geological disposal) or the non-controllable releases to the biosphere (for near-surface disposal) and the undetermined characteristics of the locations (for mobile sources), which are not considered in the present guidance. Specific guidance on assessment for disposal and transport is given in [16] and [17].

1.15. The radiological environmental impact assessment, as described within this Safety Guide is intended to be prospective in nature. For example, it can be used prior to siting, when granting an authorization during construction and prior to operation, or prior to a decommissioning process. The prospective assessment as described in this Safety Guide can serve multiple purposes including, establishing the initial authorization basis with respect to public and environmental protection, and as an important input into the process of authorizing

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[4] Facilities and activities needing radiological environmental impact assessment are those where radioactive material is produced, processed, used, handled or stored on such a form and scale that consideration of the possible impact on the public and the environment is required. Examples of facilities are: nuclear installations (including nuclear power plants; research reactors, radioisotopes and sources production facilities, spent fuel storage and reprocessing facilities, facilities for the enrichment of uranium, nuclear fuel fabrication facilities, some mining and raw material processing facilities such as open-pit uranium mines, facilities for the milling or processing of uranium ores; predisposal processing of radioactive waste facilities, nuclear fuel cycle related research and development facilities. Activities may include: the use of unsealed radiation sources for industrial, research and medical purposes and the decommissioning of certain facilities.

[5] Safety analysis is part of the safety assessment for facilities and activities required by the IAEA Safety Standards [1, 5].

[6] IAEA Safety Glossary define ‘accident’ as any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

controlled discharges. The process to establish discharge limits and optimize the protection of the public is covered in a separate Safety Guide [8]. The assessment could also be applied for those existing facilities requesting changes in their operational processes before the implementation of any significant change affecting the level of discharges or of potential releases to the environment, or, if deemed necessary, in the framework of periodic safety reviews.

1.16. The radiological environmental impact assessment described in this Safety Guide is not intended to assess retrospectively the radiological impact from discharges during operations or the consequences resulting from an actual accident. Nevertheless, the prospective assessment of potential exposures could provide preliminary information to be used in assessing the hazards and the related consequences for the purpose of establishing adequate level of emergency preparedness and response [18].

1.17. The prospective assessment of potential exposures for facilities and activities, as described in this Safety Guide, may require that accidents with very low probabilities of occurrence leading to radiological consequences for the public and the environment are considered and criteria for potential exposures are fulfilled. However, even if a facility or activity meets these criteria, it does not preclude the need for an assessment of hazards in relation to preparedness and response for a nuclear or radiological emergency, in line with requirements in Ref. [18]. Other aspects of the consequences of large accidental releases to the environment such as social and economic effects and other effects on the environment and on ecosystems are out of the scope of this Safety Guide.

1.18. This Safety Guide does not discuss in detail the specifications and characteristics of the events and accidents to be considered during the assessment of potential exposures to public, nor the methodology for their selection and analysis; such specification, characterization resulting from a systematic analysis should be done in the framework of safety assessment for facilities and activities [5].

1.19. This Safety Guide is focused on defining a general framework and discussing the general aspects of the methodologies for the prospective radiological environmental impact assessments, and does not discuss in detail the models to be used or the collection and use of data from radiological environmental monitoring programmes [1], which are normally undertaken at pre-operational and operational stages[7]. For the purpose of this Safety Guide, it is assumed that monitoring programmes at the pre-operational and operational stages exist (or will exist) and provided (or will provide) the necessary information for adequate dose estimations and to verify that the models and assumptions used in the prospective assessments are correct. The prospective assessment as described in this Safety Guide should also be used to inform the definition or upgrade of the site-specific environmental monitoring programme. The IAEA provides guidance for source and environmental monitoring programmes in Refs. [19] and [20].

[7] Monitoring programmes at the pre-operational stages must be defined, for instance, to establish baselines of activity concentrations in environmental media and to provide information and data for dose assessment purposes [19]. During the operation of the facility or the conduct of the activity monitoring programmes must be in place to verify compliance, to check the conditions of operation, to provide warning of unusual or unforeseen conditions and to check the predictions of environmental models [19].

1.20. The Safety Guide does not cover occupational exposures (i.e. of workers) or medical exposures (i.e. of patients). These categories of exposures and their inclusion in the authorization process are discussed in separate guidance provided by the IAEA [21, 22].

1.21. This Safety Guide only covers the assessment of the risk of radiological impacts to the health of individuals in the members of the public due to radiation exposures during normal operations and due to potential exposures. The assessment of the level of protection of members of the public in accordance with GSR Part 3 [1] can be assumed, in most of the instances, sufficient to provide for an adequate protection of the ecosystems in environment. For situations where the national or international regulatory frameworks consider necessary the explicit assessment of the effects of radiation on the exposed flora and fauna, guidance is presented in an Annex I.

1.22. This Safety Guide does not discuss the process of 'iteration and design-optimization'[8] of the facility or activity, which is normally conducted within the safety assessment framework [9]; however radiological environmental impact assessments as described in this Safety Guide can serves to that process.

1.23. Optimisation of safety and protection[9] (in the context of requirements in GSR Part 3 [1] and the recommendations of ICRP [3]) includes not only protection of the public but the safety features of the facility or activity and the protection of workers, and therefore is out of the scope the present Safety Guide, which only covers public protection. Optimization of the protection of public, in connection with the establishment of discharge limits for facilities and activities, is discussed in other IAEA Safety Guide [8]; the result of a radiological environmental impact assessment, as described in the present Safety Guide, is a necessary input for the subsequent process for establishing discharge limits.

1.24. The possible non-radiological impacts of facilities and activities, which are generally included in an EIA, such as the impacts on the environment from discharges of other hazardous substances (i.e. chemicals) and heated water, and of the construction of a facility, impacts on features of the environment such as historic monuments and cultural places or impacts on endangered species or the landscape, as well as other social and economic impacts, are not considered in the present Safety Guide. States are subject to the nationally and internationally relevant treaties, conventions, codes of conduct and regulations. States also have an obligation of diligence and duty of care and are expected to fulfil their national and international undertakings and obligations. International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection [2].

STRUCTURE

1.25. Section 2 gives explanations of the main concepts and terms used in the Safety Guide. Section 3 describes the safety requirements related to the prospective radiological environmental impact assessment for protection of the public and protection of the

[8] There could be a number of iterations in the safety assessment, and the iteration needs to proceed only until the assessment is judged to be adequate for its purpose.

[9] This could include, for example, evaluation of different treatment options of radioactive waste, taking into account safety, economic, radiological, environmental and societal factors.

environment for governments, national regulatory bodies and licensees stemming from other IAEA standards. Section 4 gives the framework in which such assessments are done. Section 5 describes the methodology needed to carry out the assessments for protection of the public for normal operations and for potential exposures and discusses the consideration of the radiological protection of the environment. Appendix I presents risk criteria discussed by relevant international organizations, which could be used as the basis to define national criteria for consideration of potential exposures. Annex I presents a complementary methodology to assess radiological protection of flora and fauna. Annex II presents considerations in the assessment of potential exposures on public. Examples of national approaches to consider exposures resulting from normal operation and potential exposures of members of the public are presented in Annex III.

2. EXPLANATION OF CONCEPTS AND TERMS

2.1. This Section provides an explanation of some of the concepts and terms used in this Safety Guide. Unless otherwise mentioned, terms are to be understood as defined in the IAEA Safety Glossary [4]. While approaches may be in principle consistent with these concepts and terminology, the use of the terms defined in this section could differ from those used in States.

PLANNED EXPOSURE SITUATIONS: EXPECTED EXPOSURES AND POTENTIAL EXPOSURES

2.2. GSR Part 3 defines a ‘planned exposure situation’ as “a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure due to a source. In planned exposure situations, exposure at some level can be expected to occur. If exposure is not expected to occur with certainty, but could result from an accident or from an event or a sequence of events that may occur but is not certain to occur, this is referred to as ‘potential exposure’ ” (GSR Part 3 para. 1.20 (a)) [1]. The magnitude and extent of these exposures can usually be predicted. Both exposures and potential exposures can and should be taken into account at the planning or design stage [6].

GOVERNMENTAL DECISION-MAKING PROCESS

2.3. In the context of this Safety Guide the term ‘governmental decision-making process’ refers to the procedures carried out at a planning stage by the government or governmental agencies, including the relevant regulatory body, to decide whether a project for a facility or an activity may be undertaken, continued, changed or stopped. It could also apply to areas of national policy such as whether to embark on a nuclear power programme [23].

2.4. A governmental decision-making process is normally conducted at the early stages of a programme of development and, mainly, for activities or facilities that are foreseen to need a thorough assessment of their possible impact to the environment. For some nuclear

installations and facilities —and other conventional installations[10]— national or international regulations identify this decision process with the term 'environmental impact assessment'[11], which is explained below.

(REGULATORY) AUTHORIZATION PROCESS (OR LICENSING PROCESS)

2.5. 'Authorization' is a term defined in GSR Part 3 as a formal procedure established in the national regulatory framework by which a regulatory body or other governmental body grants written permission, at different stages of the lifetime of a facility or the development of an activity [1].

2.6. The authorization of a facility or an activity, in the form of a registration or licence [1], could be granted for design, siting, construction, operation, decommissioning activities and when modifications in the conditions of operation of activities and facilities are considered.

ENVIRONMENTAL IMPACT ASSESSMENT

2.7. The term 'environmental impact assessment' (EIA) is not defined in the IAEA safety standards although it is included in many international instruments and national legislations and regulations [24–31]. In the context of this Safety Guide, an EIA refers to a procedure within a governmental decision-making process for identifying, describing and assessing prospectively the effects and the risk of effects of particular proposed activity or facility on aspects of environmental significance[12].

2.8. The effects related to radioactive releases from activities and facilities to the environment likely to be considered in an EIA generally include radiological effects on human health and, in some cases, radiological effects on flora and fauna. Non-radiological impacts which are generally included in an EIA are not considered in the present guidance but are subject to the nationally and internationally applicable regulations.

2.9. In general, an EIA requires the involvement of the organizer of the proposed activity or facility, relevant governmental agencies, the regulatory body and a number of interested parties [24, 27–31].

ENVIRONMENT AND PROTECTION OF THE ENVIRONMENT

2.10. GSR Part 3 [1] defines the environment as the "conditions under which people, animals and plants live or develop and which sustain all life and development; especially such

[10] Examples of other installations usually identified as needing a governmental decision-making process are crude oil refineries, chemical installations, large dams, electrical power lines, wind farms, motorways, trade ports and thermal power stations.

[11] The term 'governmental decision-making process' encompasses or is related also to different terms used by the States with similar or equivalent meanings, such as 'decision-in-principle', 'environmental impact statement, and, in some cases, 'justification' processes.

[12] Publication in the IAEA Nuclear Energy Series [32] provides information on EIA in the framework of the development of a new nuclear programme.

conditions as affected by human activities". Usually, environment includes ecosystems which comprise biotic and abiotic components.

2.11. The Fundamental Safety Principles [2] state that "the present system of radiation protection generally provides appropriate protection of ecosystems in the human environment against harmful effects of radiation exposure. The general intent of the measures taken for the purposes of environmental protection has been to protect ecosystems against radiation exposure that would have adverse consequences for populations of a species (as distinct from individual organisms)".

2.12. GSR Part 3 [1] specifies that the protection of the environment means protection and conservation of non-human species, both animal and plant, and their biodiversity; environmental goods and services such as the production of food and feed; resources used in agriculture, forestry, fisheries and tourism; amenities used in spiritual, cultural and recreational activities; media such as soil, sediments, water and air; and natural processes.

2.13. The system of protection and safety described in GSR Part 3 [1] defines a framework to assess, manage and control exposure to radiation for humans which generally provides for appropriate protection of the environment from harmful effects of ionizing radiation. However, the introduction in GSR Part 3 [1] acknowledges that some national regulations may require the explicit demonstration (rather than the assumption) of the protection of the environment. GSR Part 3 [1] introduction also mentions that the assessment of impacts on the environment needs to be viewed in an integrated manner with other features of the system of protection and safety and that the approach to the protection of people and protection of the environment is not limited to the prevention of radiological effects on humans and on other species [1].

2.14. Finally, GSR Part 3 introduction states that, the protection of the environment is an issue necessitating assessment, allowing for flexibility in incorporating into decision making processes the results of environmental assessments that are commensurate with the radiation risks [1].

RADIOLOGICAL ENVIRONMENTAL IMPACT ASSESSMENT

2.15. The requirement to assess radiological environmental impacts is identified in GSR Part 3 [1], but the term 'radiological environmental impact assessment' is not formally defined. For the purpose of this Safety Guide, radiological environmental impact assessment is taken to be a form of prospective assessment that identifies the target(s), assesses the expected and analytical conceivable radiological impacts, and compares the results with predefined criteria. Within this Safety Guide, 'radiological impact' is taken to mean the estimated risk of effects of radiation dose that may be caused by releases from a proposed facility or activity on human health and, if deemed necessary, other elements in the environment, for example flora and fauna. A radiological environmental impact assessment may be seen as one component of an EIA (as described above) in the context of planning for nuclear facilities and activities.

MEMBERS OF THE PUBLIC

2.16. GSR Part 3 [1] defines a member of the public as "in a general sense, any individual in the population except when subject to occupational exposure or medical exposure". The

IAEA Safety Fundamentals, Principle 7, states that safety standards apply not only to local populations but also to populations remote from facilities and activities. In addition, where effects could span generations, subsequent generations have to be adequately protected without any need for them to take significant protective actions [2].

3. SAFETY REQUIREMENTS RELEVANT TO PROSPECTIVE RADIOLOGICAL ENVIRONMENTAL IMPACT ASSESSMENT

3.1. The following paragraphs contain extracts from the IAEA Fundamental Safety Principles [2], GSR Part 3 [1] and other IAEA standards [5, 33] illustrating the relevant safety requirements to conduct an assessment of the protection of the public and protection of the environment for planned exposure situations. The requirements are addressed in in Section 4 and 5 of this Safety Guide.

LIMITATION OF DOSES AND RISK

3.2. The GSR Part 3 [1] states that there is a need to control and minimize the radiological impact to members of the public and the environment.

3.3. The IAEA Fundamental Safety Principles [2] establish, among others, principles for ensuring the protection of the public and the environment, now and in the future, from harmful effects of ionizing radiation, and the need for "doses and radiation risks to be controlled within specified limits" (Principle 6). These principles apply to situations involving exposure to, or the potential for exposure to, ionizing radiation[13].

This is discussed in Section 5 which describes the methodology for an assessment of the level of protection of the public and the environment including the use of dose and risk criteria.

RESPONSIBILITIES

3.4. Requirement 7 of GSR Part 3 [1] (paragraph 3.8) states that "any person or organization applying for authorization:

> (a) … shall, as required by the regulatory body, have an appropriate prospective assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity".

This is discussed in Section 4 which gives the context in which an assessment is done and Section 5 which describes the methodology for an assessment of the level of protection.

3.5. Requirement 9 of GSR Part 3 [1] (paragraph 3.15) gives the responsibilities of registrants and licensees in planned exposure situations. It states that "registrants and licensees:

[13] In contrast, dose and risk limitation is not applied to emergency exposures situations, where reference levels are used.

(a) … shall, for the sources for which they are authorized and for which the regulatory body requires a prospective assessment to be made for radiological environmental impacts, conduct such an assessment and keep it up to date".

(b) … shall assess the likelihood and magnitude of potential exposures, their likely consequences and the number of persons who may be affected by them.

These requirements are covered in Section 5 which describes the methodology for an assessment of the level of protection.

3.6. Requirement 12 of GSR Part 3 states that "the government or the regulatory body shall establish dose limits for… public exposure, and registrants and licensees shall apply these limits". Section 5 addresses this requirement.

3.7. Requirement 29 of GSR Part 3 (paragraph 3.120), which relates to responsibilities specific to public exposure, states that "the government or regulatory body shall establish or approve constraints on dose and on risk to be used in the optimization of protection and safety for members of the public". Paragraph 3.123 states that "the regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharge. These operational limits and conditions:

(a) … shall take into account the results of the assessment of the potential radiological environmental impacts undertaken in accordance with national requirements" .

The definitions of and use of constraints on dose and risk are discussed in Section 5.

ASSESSMENT FOR PROTECTION OF THE PUBLIC AND PROTECTION OF THE ENVIRONMENT

3.8. Principle 7 of the IAEA Fundamental Safety Principles [2] states that: "People and the environment, present and future, must be protected against radiation risks".

3.9. The consideration of the protection of the environment is contemplated in the IAEA safety standards [1, 2]. Requirement 31 of GSR Part 3 relates to radioactive waste and discharges[14]. Paragraph 3.132 of GSR Part 3 states that "registrants and licensees, in cooperation with suppliers, in applying for an authorization for discharges, as appropriate:

(a) Shall determine the characteristics and activity of the material to be discharged, and the possible points and methods of discharge;
(b) Shall determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public;

[14] Some aspects of assessment of radiological impact to public and the environment in general are included in Requirement 31 in GSR Part 3 [1]. However, the main objective of Requirement 31 is to establish authorized discharge limits. Despite a radiological environmental impact assessment as described in this Safety Guide must be an input for establishing discharge limits, the procedure for authorizing discharge limits is not specifically addressed in this Safety Guide and it is discussed in detail in the IAEA Safety Guide on regulatory control of discharges [8].

(c) Shall assess the doses to the representative person due to the planned discharges;
(d) Shall consider the radiological environmental impacts in an integrated manner with features of the system of protection and safety, as required by the regulatory body".

These elements are addressed in Section 5 which deals with the methodologies for assessing doses to members of the public.

ASSESSMENT AND CONTROL OF POTENTIAL EXPOSURE

3.10. Paragraph 3.24 of GSR Part 3 [1] establishes that "registrants and licensees shall ensure that all relevant factors are taken into account in a coherent way in the optimization of protection and safety to contribute to achieving the following objectives:

(a) To determine measures for protection and safety that are optimized for the prevailing circumstances, with account taken of the available options for protection and safety as well as the nature, likelihood and magnitude of exposures;

(b) To establish criteria, on the basis of the results of the optimization, for the restriction of the likelihood and magnitudes of exposures by means of measures for preventing accidents and for mitigating the consequences of those that do occur".

3.11. Paragraph 3.15 of GSR Part 3 [1] establishes that "Registrants and licensees:

(e) … shall assess the likelihood and magnitude of potential exposures, their likely consequences and the number of persons who may be affected by them".

3.12. Requirement 6 of GSR Part 4 [5] states that "the possible radiation risks associated with the facility or activity shall be identified and assessed". These include "the level and likelihood of radiation exposure of […] the public, and of the possible release of radioactive material to the environment, that are associated with anticipated operational occurrences or with accidents that lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation".

3.13. Requirement 13 of GSR Part 3 [1] states *inter alia* that "safety assessment shall:

(a) Identify the ways in which exposures could be incurred....

(b) Determine the expected magnitudes and likelihoods of exposures in normal operations and, to the extent reasonable and practicable, make an assessment of potential exposures".

The assessment and control of potential exposure is addressed in Section 5 and discussed in Appendix II of this Safety Guide.

GRADED APPROACH

3.14. Principle 5 of the Fundamental Safety Principles (paragraph 3.24 in the SF) [2] states that "the resources devoted to safety by the licensee and the scope and stringency of the regulations and their application, have to be commensurate with the magnitude of the possible radiation risks and their amenability to control".

3.15. Requirement 1 of GSR Part 4 (paragraph 3.1) [5] states that to apply Principle 5 "a graded approach needs to be taken in carrying out the safety assessments for the wide range of facilities and activities … owing to the very different levels of possible radiation risks associated with them".

3.16. Requirement 6 of GSR Part 3 [1] states that "the application of the requirements of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the magnitude and likelihood of the exposures".

3.17. Requirement 1 of GSR Part 4 [5] (paragraph. 3.4) states that "other relevant factors, such as the maturity or complexity of the facility or activity, are also to be taken into account in a graded approach to safety assessment". It also states (paragraph. 3.6) that "the application of the graded approach needs to be reassessed as the safety assessment progresses and a better understanding is obtained of the radiation risks arising from the facility or activity. The scope and level of detail of the safety assessment are then modified as necessary and the level of resources to be applied is adjusted accordingly".

The graded approach, as applied to a radiological environmental impact assessment, is discussed further in Section 4.

TRANSBOUNDARY IMPACTS

3.18. Requirement 29 of GSR Part 3 [1] addresses the issue of exposure outside the territory under the jurisdiction or control of the State in which the source is located[15]. Paragraph 3.124 requires that "when a source within a practice could cause public exposure, the government or the regulatory body shall:

> (a)…ensure that the assessment of the radiological impacts includes those impacts outside the territory or other area under the jurisdiction or control of the State.
>
> (b)…arrange with the affected State the means for exchange of information and consultations, as appropriate".

This is discussed in Section 5.

4. FRAMEWORK FOR PROSPECTIVE RADIOLOGICAL ENVIRONMENTAL IMPACT ASSESSMENT FOR FACILITIES AND ACTIVITIES

4.1. The government or the regulatory body should identify in advance the types of facilities and activities for which a radiological environmental impact assessment is required or the criteria to decide, on a case-by case basis, the need (or not-need) of such an assessment.

[15] The consideration of the protection of public and the environment at the transboundary level and the obligations for assessing the impacts and sharing information between States should also be included within the broader context of relevant international agreements and conventions (e.g. UNCLOS 1982 [25], Espoo 1991 [24], Aarhus 1998 [26] and Article 37 of the EURATOM Treaty [34]).

In general, X-Ray generators, small laboratories, medicine departments or industrial applications using sealed sources, and any other facilities or activities where radiation sources are used processed or stored in a form and scale that impact to public and the environment is not foreseeable during normal and accidental situations, should be excluded from the need of such an assessment.

4.2. The level of complexity of a radiological environmental impact assessment should also be defined by the government or the regulatory body in the national legal framework or regulations. Account should be taken on the characteristics of the activity or facility, based on considerations of the risk to public and the environment due to the expected and potential exposures. Activities and facilities which are exempted[16] from regulatory control should not require a radiological environmental impact assessment for authorization, even if a generic assessment of the impact to public and environment may have been performed to support the conclusion on exemption.

4.3. The approaches used for a radiological environmental impact assessment (for example: the assumptions, the conceptual and mathematical models and the input data) may vary with the complexity of the facilities and activities and the associated exposure scenarios, and should be defined applying the concept of a graded approach. For the sake of clarity, assessments discussed in this Safety Guide are sometimes categorized as either simple or complex. However, it is recognized that these terms are the two ends of the range of possible assessments and there are a large number of activities, and facilities that require an assessment falling between these two categories.

ASSESSMENT FOR THE (REGULATORY) AUTHORIZATION PROCESS

4.4. Factors which are important to define the need and complexity of the environmental radiological impact assessment within a (regulatory) authorization process are: the source term[17], the level of expected doses, the safety characteristics of the activity or facility, the characteristics of the location, the national licencing regulations for each type of facility and activity and the stage in the authorization process. The applicant should consider those factors and present a proposal to the regulatory body for review and agreement. States may consider that, for certain facilities or activities, the level of detail of the assessment could be defined a priori by the regulatory body.

4.5. Factors and elements in Table 1 are not ranked in order of importance and should be used as general guidance as to whether a simple or complex radiological environmental impact assessment might be appropriate. In principle an assessment for the authorization of a nuclear facility requires a high degree of complexity, while for an activity or facility operating with a small inventory of radionuclides simpler analysis may be justified.

[16] The concept of exemption from the need of regulatory control and the radiological criteria for exemption of practices is established in GSR Part 3 [1].

[17] 'Source term' is the amount and isotopic composition of material released (or postulated to be released) from a facility used in modelling releases of radionuclides to the environment [4]. It is also applicable to certain activities and can be defined together with its physical and chemical properties relevant for environmental dispersion.

TABLE 1. EXAMPLES OF FACTORS AFFECTING THE REQUIRED LEVEL OF COMPLEXITY OF A RADIOLOGICAL ENVIRONMENTAL IMPACT ASSESSMENT[18]

Factor		**Element**
Facility/Activity characteristics	Source term	Radionuclides
		Quantity (both activity and mass/volume)
		Form (chemical/physical make up)
		Geometry (size, shape, height of release)
		Potential for release: source term varies significantly between normal operation and accidents
	Level of expected doses from normal operations or projected doses from potential exposures	Preliminary assessments or previous assessments for similar facilities
	Safety characteristics of the activity or facility	Types of safety barriers and engineering features present in the design
		Potential for severe accident scenarios
Location characteristics		Characteristics of environment around the facility (geology, hydrology, meteorology, morphology, biophysical)
		Presence of receptor (people, flora and fauna)
		Exposure pathways
		Land use (agriculture)
		Characteristics of other installations in the vicinity and possible natural and man-made external events (for examples, earthquakes, industrial accidents)
Characteristics of authorization process for the particular activity or facility		Requirement of regulations (licensing requirements)
		Stage of the authorization process

4.6. For nuclear installations — for example nuclear power plants and reprocessing facilities— there are likely to be a number of stages in the (regulatory) authorization process [35]. During those stages the radiological environmental impact assessment may be updated as more specific data is obtained; the applicant or the organization responsible for the nuclear installations should ensure that a prospective assessment for the protection of public and environment is adequately provided, at the different stages, for consideration of the regulatory body.

4.7. Figure 1 (adapted from [35]) presents schematically the stages in the lifetime of a nuclear installation. All the assessments conducted in the stages previous to and during the operation of a nuclear installation are basically the same or very similar, incorporating more details and specific data —to reduce the level of uncertainty where possible— and reviewing the models and assumptions when this is deemed necessary. The vertical arrows in full indicate the stage at which the assessment may be discussed with the regulatory body and, finally, previous to operation, when the final assessment is ready, submitted for approval. The vertical dashed lines indicate where a reviewed assessment may be submitted to the regulatory body if significant changes have occurred during the operational stage. The horizontal arrow indicates the evolution of time.

[18] The list provided in Table 1 is not exhaustive, and judgement on the significance of these factors when selecting the type of assessment should be made by experts in nuclear and radiation safety in the applicant' organization and the national regulatory bodies.

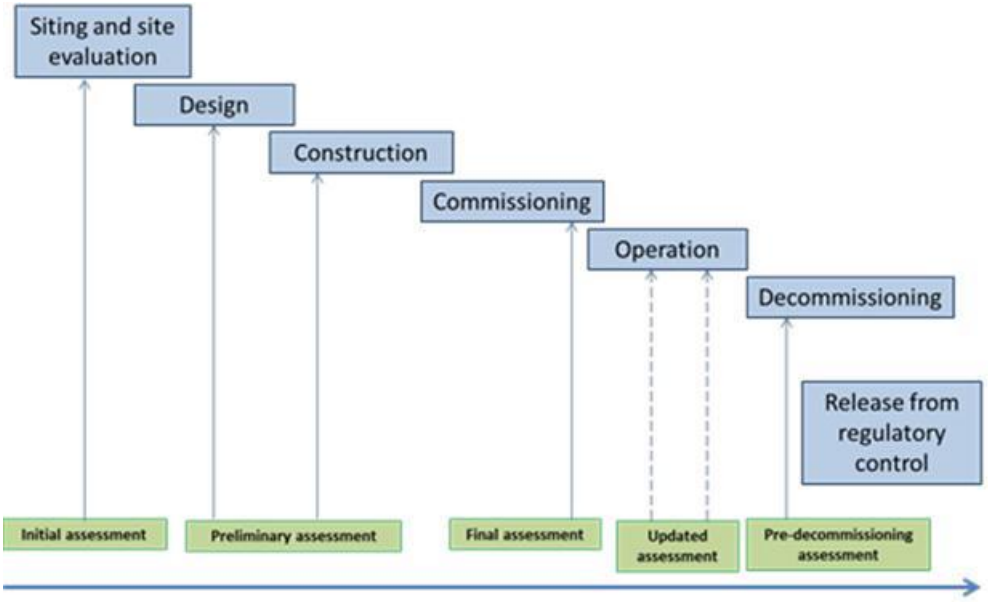

FIG. 1. Stages in the lifetime of a nuclear installation where a prospective assessment for the protection of public and protection of the environment might be input into the authorization process.

4.8. An initial assessment using regional or generic data could be conducted during the stage of siting and site evaluation for identification of potential regions or potential sites for the facility or activity. During this stage, different technologies could also be still under scrutiny.

4.9. Once a site or a reduced number of sites are selected, and the technology is more specified (e.g. the type of nuclear power plant is defined) a preliminary assessment for that particular location(s) is normally done using the available information. In general, during the construction period more information relevant for the assessment is collected, including —where this is deemed necessary— from the results of local measurements and surveys to obtain site-specific data,. The data and the models used for the assessments should evolve in order to be able to produce a final assessment at some point in the commissioning stage, before the request of endorsement or authorization to the regulatory body is done.

4.10. The radiological environmental impact assessment performed before starting the operation of a facility or conducting an activity should be used as an input to determine operational magnitudes related to public protection, for instance, the authorized radioactivity discharge limits. Guidance on establishment of authorized discharge limits is presented in a separated IAEA Safety Guide [8].

4.11. For facilities already in operation and activities being conducted, a subsequent update of the safety assessment —e.g. a periodic safety assessment review— is required [5]; this review should include the consideration of the possible changes in the assumptions used to perform the prospective radiological environmental impact assessment. The radiological environmental impact assessment may need to be re-evaluated if there are significant changes in the facility or activity characteristics or in the location characteristics (see Table 1).

4.12. At the end of a decommissioning stage or before release of a site from regulatory control a radiological environmental impact assessment is also expected. However, for most of the activities and facilities, typically no releases or potential exposures are involved after decommission and the methods for exposure estimation and criteria could be different (for example, the estimation of the doses should be based mainly on environmental monitoring data and the dose criteria could be below dose limits and constraints used for the operational stage). A particular situation could be that of some activities and facilities involving large areas —like uranium mining and milling— after decommissioning, where source terms and impacts to the environment could still be foreseen. These situations should be analysed on a case by case basis.

ASSESSMENT AS PART OF A GOVERNMENTAL DECISION-MAKING PROCESS

4.13. A radiological environmental impact assessment is required as part of a governmental decision-making process for certain facilities and activities, and may be included, for example, within an EIA process. The facilities and activities needing an EIA, and its level of complexity, should be defined by the government or regulatory body on the basis of the possible significant effects on the environment during the normal operation and the conceivable accidental conditions, considering, for example, the factors indicated in Table 1[19].

4.14. The government or the regulatory should established thresholds and/or criteria at a level such that all projects of a certain type of facilities or activities would be exempted in advance from the requirement of an EIA, considering that impact is not expected either for normal operation or conceivable accidental scenarios.

4.15. A radiological environmental impact assessment done within an EIA process is normally done at early stages of the development and, typically, has a lower level of details and uses less specific data than an assessment conducted for a (regulatory) authorization process; however it should be consistent.

4.16. Unless defined in the applicable national or international regulations, the level of complexity for the radiological environmental impact assessment for an EIA should be proposed by the applicant and agreed by the nuclear regulatory body(s) in the country in discussion with other governmental authorities or agencies. For some types of facilities, for example hospitals or small laboratories, there may be no requirement for a detailed radiological environmental assessment for a governmental decision-making process, because significant impact to the environment is not expected either for normal releases or accidental scenarios; however, national competent authority may establish their own requirements for activities or facilities which need such an assessment.

4.17. A radiological environmental impact assessment during a governmental decision-making process could have a single or multiple phase(s). The initial assessment may be relatively descriptive in nature and based on generic data and conservative assumptions, whilst further assessment may include more realistic models and site-specific information.

[19] Some international directives, like the Convention on Environmental Impact Assessment in a Transboundary Context [24] and the EU Directive on the Assessment of the Effects of Certain Public and Private Projects on the Environment [27] identify the types of facilities and activities needing an environmental impact assessment.

Generic assessments for similar facilities already in operation in equivalent sites can provide useful information.

ASSESSMENTS FOR OTHER PURPOSES

4.18. Outside governmental decision-making or (regulatory) authorization processes, operators can conduct a radiological environmental impact assessment with the objective of introducing improvements in the safety systems of a facility or an activity. For example, as part of a process to evaluate the safety performance of a facility or an activity, an operator can evaluate the systems to reduce radioactive releases to the environment (i.e. normal operation aerosol filters or decay tanks) or the systems to mitigate releases during accidental conditions (i.e. emergency filters). When performing such assessments, the same approaches as described in this safety guide should be applied to ensure that all the aspects of public and environmental protection are considered, including the expected exposures and the potential exposures.

COMMUNICATION OF RESULTS

4.19. Requirement 36 of GSR Part 1 [33] requires that the regulatory body, either directly or through the applicant of a facility or activity, shall establish effective mechanism of communication to interested parties about the possible radiation risks associated with the facility or activity and about the processes and decisions of the regulatory body, in accordance with a graded approach. The factors in Table 1 should be considered when establishing the contents and the level of detail in the reports for information provision to the relevant interested parties. Depending on the importance of the enterprise, the regulatory body should involve governmental authorities when such communication is considered necessary for effectively performing the public informational functions of the regulatory body. Ref. [36] provides guidance on communication and consultation with interested parties by the regulatory body.

4.20. The prospective radiological environmental impact assessment results in technical documents which are generally intended for people with expertise in the matter. Normally these are experts in nuclear safety and radiation protection from regulatory bodies or technical support organizations, public health or environment agencies. The assessment should be well documented and transparent for a broader audience, which may not have a highly specialized expertise, for example, the public, government departments and ministries not directly involved in safety and radiation protection issues and others. Information on the assessment should be made available in appropriate technical language. In addition to that a non-technical summary that condenses the relevant chapters of the more technical reports and outlines the key findings from the assessment could be useful for some of the interested parties.

4.21. The communication of the results is equally as important and challenging as the completion of technically sound radiological environmental impact assessments. In order to put the results in the adequate perspective, essential information on radiation effects and the safety aspects related to design, operation, maintenance and surveillance of activities and facilities should be included together with the specific results the in the reports produced.

4.22. Where the results of an assessment indicate that the information is relevant across national boundaries, this information should be shared with the States concerned. The State

where the activity or facility is located should arrange with the interested States the means for exchange of information and consultations, as appropriate.

4.23. The information used as basis for an assessment as described in this Safety Guide could have commercial and security implications (for example, plans for the facility layout and information on plant accident sequences). This information should be available only to the regulatory authorities and other governmental agencies and should be treated confidentially. Normally the government, in consultation with the national regulatory body and other relevant national organizations, should establish which information should be made available publicly. The responsibility to ensure the soundness of the restricted information should remain with the governmental agencies with functions related to safety and security. The restriction of access to certain sensitive information should be clearly explained so that it is not perceived by the interested parties as concealing information that is relevant for estimating and understanding the radiation risks to people and to the environment.

5. METHODOLOGY FOR THE ASSESSMENT

GENERAL CONSIDERATIONS

5.1. This Section presents a methodology to assess the level of protection of public against exposures due to normal operation and potential exposures from facilities and activities and discusses the consideration of the radiological protection of the environment.

5.2. Since an assessment for protection of the public and protection of the environment within this Safety Guide is prospective in nature, reliance will have to be placed on mathematical modelling for evaluating, for example, the dispersion of radionuclides in the environment, the transfer through environmental compartments, the transfer to humans and to the human food-chain and, finally, the radiation doses resulting from the associated external radiation or from the uptake of radionuclides. The models should be appropriate for the situation in which they are being applied, ensuring reasonable accuracy. Model assumptions and parameter choices should be sufficiently described and referenced to be transparent and allow independent verification.

5.3. Where possible, the selected models should be supported through comparison of their results with data resulting from measurements at similar exposure scenarios or, at least, by means of benchmarking procedures against other appropriate models. Section 1 also mentions the need for establishing environmental monitoring programmes for the operational phase of an activity or facility, not only to verify compliance with discharge and dose limits but to ensure that the assumptions used in the prospective assessment were accurate or conservative (i.e. over-protective) in nature.

5.4. Different methods, including calculation tools and input data, can be used to carry out radiological environmental impact assessment [11, 12]. The applicant should define the level of complexity and details in the methods used considering the characteristics of the facility or activity and the location (see Table 1 in Section 4). The national regulatory body needs to be satisfied that the methodology adopted is adequate for the purposes of national practice and should decide —in discussion with the applicants of the facility or activity and other interested parties — which methodology is suited to carry out a particular assessment.

5.5. One consideration when deciding on the methods for a radiological environmental impact assessment is the balance between the amount of effort and the level of detail required. For example, for an installation with low levels of discharges and/or low potential for accidents with consequences to the public and the environment, the use of detailed methods would not be necessary. For these types of installations, regulatory bodies, vendors or professional associations may develop generic guidance with simple and cautious calculation methods that can be used for the assessments by the applicants.

5.6. For facilities needing complex assessments, the level of detail in the models and the data used for the assessment may evolve during the governmental decision-making process and the (regulatory) authorization process.

ASSESSMENT FOR PROTECTION OF THE PUBLIC FOR NORMAL OPERATION

5.7. Facilities and activities that use or process radioactive sources or materials, are designed, constructed, commissioned operated or conducted, maintained and decommissioned —and regulated throughout all these stages, in order to prevent or minimise releases of radioactive materials to the environment. However, very low amounts of radionuclides residues can be found in some of the gaseous or liquid effluents resulting from the normal operations, implying negligible to very low doses to the public[20]. Nevertheless, in order to control the exposure to the public, in accordance with the safety principles in [2] and the safety requirements in GSR Part 3 [1] (discussed in Section 3), there is a need to conduct assessments that include prospective estimations of the possible dose to members of the public and compare the results to defined criteria.

Procedure of the assessment

5.8. The radiological environmental impact assessment for protection of the public for normal operation uses estimations of the dose to the public resulting from the controlled releases resulting from the operation of facilities or conduct of activities. Figure 2 gives schematically[21] the components of such assessment. In general terms, the first stage of the assessment is to characterize the source of radiation related to public exposures; in the second stage dispersion in the environment and the transfer in the environmental compartments relevant for the identified exposure pathways and the location are considered. The activity concentrations estimated in a number of environmental media are then combined with relevant habit data and time-occupation factors to calculate intakes of radionuclides (internal exposure) or external radiation (external exposure) to a representative person. Intakes and external radiation are combined with dosimetric data to calculate doses to the representative person for comparison with relevant criteria, for example dose constraints.

[20] Due to the low activity concentrations and high volumes involved, it would be technically difficult to retain all this residues or may have an excessive and unjustified cost from the radiological protection perspective.

[21] The Safety Guide is intended to provide a general framework for radiological impact assessment. This and other figures in this Safety Guide are conceived to illustrate the elements of such assessments, facilitate their discussions and are not proposed to be used as detailed procedure. Important steps which are not discussed but should be considered when performing the assessments are, i.e., selection of computer codes, uncertainty analysis, verification and QA/QC control.

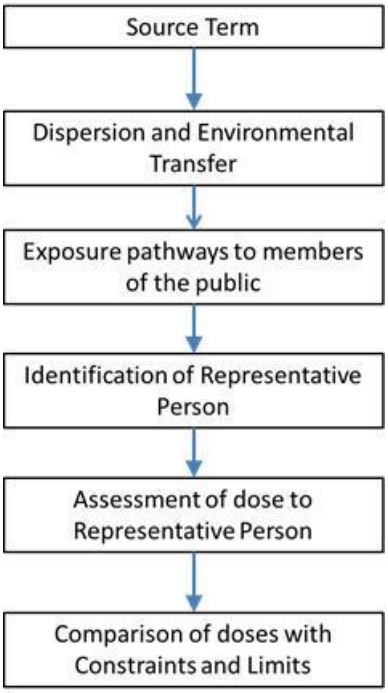

FIG. 2. Components of an assessment for protection of the members of the public for normal operations.

The different components of the assessment presented in Figure 2 are discussed in the following paragraphs 5.9 to 5.38.

Source term

5.9. The source term selected for a radiological environmental impact assessment should be appropriate for the type of facility or activity being considered. All relevant radionuclides, from a radiological point of view, should be identified along with the discharge route and the physical and chemical properties relevant for environmental transfers of these radionuclides. Releases to the atmosphere and to the aquatic environment should be considered, as appropriate.

5.10. In some cases, for instance at the governmental decision-making process or initial stages of a (regulatory) authorization process, generic source terms for the postulated facility or activity could be used, based on preliminary estimations, published data or on the experience from similar installations. Information on generic source terms for normal operation of nuclear reactors can be found in [37, 38]. Later, when more details are known about the facility or activity design and operation, the source term should be more accurately characterized by means of an appropriate engineering analysis.

5.11. The total estimated releases should be provided over the period required by the regulatory body — this is generally given in terms of activity released per year of operation. A radiological environmental impact assessment will typically assume that the discharges are continuous and constant over a year. Where this assumption may not be valid, because significant variation in the discharges over a short time period are expected — e.g. during refuelling of reactors or for typical iodine-131 discharges to sewer from thyroid treatment

departments at a hospital— then the effects due to short-term releases will need to be considered.

Dispersion and transfer in the environment

5.12. A variety of models and data are required to predict the dispersion and transfer of radionuclides through the environmental media and to the representative person. The processes more relevant to dose estimations should be identified and a conceptual model[22] should be elaborated. The conceptual model should represent the identified relevant dispersion and transfer pathways.

5.13. Activity concentrations in environmental media, resulting from the postulated releases of radioactive materials, such as in air, in sediments, in soil, in water, and in biota should be estimated through the use of mathematical models. Environmental models to assess dispersion and transfers of varying levels of complexity have been developed by several authors and were compiled and adapted by the IAEA [11, 12]. The regulatory body should confirm if models and data presented by the applicant are appropriate for the assessment under consideration, taking into account the characteristics of the installations and the factors discussed in Section 4.

5.14. Two possible approaches of models and data for the assessment are: (i) a generic (and simpler) methodology, which takes account of dilution, dispersion and transfer of radioactive releases into the environment with cautious assumptions; or (ii) a specific (and more detailed) methodology, using partial or total site-specific data to estimate activity concentrations in different environmental media, with more realistic assumptions. In both cases, models should be able to estimate spatial distribution and temporal variation of activity concentrations in the environment. The complexity of the model used should be commensurate with the possible level of environmental impact of the installation.

5.15. For assessment of exposures to members of the public the models should be able to simulate the dispersion, dilution, transfer accumulation and decay (or other removal mechanism), as necessary. This includes the following processes:

(a) Atmospheric dispersion;
(b) Deposition of radionuclides from the atmosphere on the ground or other surfaces;
(c) Dispersion of radionuclides in surface water (freshwater, brackish or marine) and ground water;
(d) Accumulation in aquatic sediments; and
(e) Transfer and accumulation of radionuclides to plants and animals in the food chain.

5.16. The models used to estimate activity concentrations in environmental media (e.g., in the air, in the aquatic media, on the ground and through the soil) should take account of the physicochemical properties of the radionuclides being released necessary to assess, for example, the effective release height, water retention or flow rate, the effects on the dispersion of effluents by nearby buildings or, in water bodies, the effect of local bathymetry, and removal/accumulation mechanisms like radioactive decay, radioactive chains, wet and dry deposition and sedimentation.

[22] A conceptual model is a representation that captures the key elements or components of a complex system, like the relationship between the released radionuclides and the environment.

5.17. For facilities or activities needing simple assessments the meteorological and hydrological conditions could be of a generic character based on bibliography or national records. The meteorological and hydrological conditions used for the more complex assessments should be appropriate and specific for the site in question and should preferably be averaged from several years of data (at least, 3–5 years). Such data may be available for the site itself or from nearby meteorological or hydrological stations.

5.18. In general, Gaussian type atmospheric dispersion models can be used [11], particularly where the geographical characteristics of the sites under consideration leads to simple dispersion scenarios (e.g. relatively flat terrains) and the representative person is located in the first 1–20 km from the release point. However, for more complex dispersion conditions, for example for installations located close to mountainous regions or places where complex local atmospheric circulations are expected, or in cases where greatest distances need to be considered, more complex dispersion models may be necessary. In any case, predictions of the dispersion models should be based on realistic assumptions as far as possible and pessimistic assumptions when uncertainties or variability in the data prevent those realistic assumptions to be considered. If the location of the facility is known at the time of the assessment, these assumptions should take account of site-specific conditions. If not, generic information at a regional level should be used until more details on the project are known.

5.19. Radionuclides may be discharged to a freshwater, estuarine or marine environment. Radionuclides discharged to water bodies are dispersed or concentrated by environmental processes like, water movement and sedimentation. Much depends on the local characteristics of the receiving environment, and it is not possible to have a totally generic model for these releases. For example, information for rivers requires at least the size of the river and its flow rate [11]. Models should be able to estimate the activity concentrations in water and in sediment. From these data activity concentrations in aquatic food, such as fish, molluscs and crustaceans, as relevant, can be estimated together with external radiation doses from exposure to sediments.

5.20. For some activities and facilities, discharges of radioactive liquids to sewerage systems may occur with the waste water being carried to sewage treatment works. When assessing discharges to sewers, the models should be able to estimate the transfer of the radionuclides to the sewerage works and their subsequent release into the environment. Radionuclides could be discharged from the sewerage works with the treated effluent, to rivers or coastal waters, where the models discussed in the paragraph above would be required. In addition, radionuclides may be associated with the sewage sludge which is managed in various ways including its reuse as a soil conditioner and fertilizer on agricultural land treatment or disposal by incineration or to a municipal waste landfill site. Appropriate models should be available for the transfer of radionuclides through terrestrial food chains and for atmospheric releases.

5.21. When radionuclides are continuously discharged they accumulate in the environment up to the point where equilibrium conditions are or can be assumed to have been reached. The activity concentrations in the environmental media used to estimate doses should be representative of the conditions when accumulation can be assumed to have reached equilibrium. Dose estimates should be calculated for the time period at which the highest radiological exposure is expected**.** For example, when a facility is expected to be operational for 30 or 40 years and the equilibrium can be assumed at the end of the operational life, the dose should be assessed at the 30th or 40th year to take this accumulation into account.

5.22. Radioactive decay chains (progeny) may need to be taken into account. In some cases, the decay products may be more radiologically significant than the parent and so it is important to consider the ingrowth. Examples of this are the uranium decay series and plutonium-241 which decays into americium-241. The assumptions and approaches to deal with progeny, including the exclusion of progeny if applicable, should be justified.

5.23. The transfer of radionuclides from environmental media to the plants and animals in the human food chain should be estimated using generic recommended transfer factors like those in IAEA publications [11, 13–15]. Those publications provide transfer factors for food in the terrestrial, marine and freshwater ecosystems. If there is a need to refine the assessment, for instance when the initial estimated doses using generic transfer factors are above or close to the dose criteria, transfer factors based on site specific measurements could be necessary. However, this could be difficult in the framework of prospective assessments. The regulatory body should decide when site specific data based on measurements should be used in an assessment. The uncertainties due to lack of site specific data on transfer parameters can be compensated by the use of generic data with conservative assumptions, whilst noting the need not to be grossly pessimistic in these assumptions.

5.24. For installations requiring complex assessment, when at the initial stages of an authorization process, a preliminary estimation of the dispersion and transfer to the environment can be done using simple cautious models and meteorological/hydrological data generic to the region (e.g. from published data or from records from the closest meteorological/hydrological stations, which may sometimes be located at tens to hundreds of kilometres from the sites). At later stages of the authorization process, meteorological and hydrological data from measurements conducted on-site or very close to the plant location should be used, as it become available. These measurements are the regular practice during site survey and construction stages. Information on the type and detail of data which should be available at the later stages of licensing process can be found in other IAEA publications [39-41].

Exposure pathways

5.25. Doses should be calculated resulting from a number of exposure pathways which are considered relevant for releases to the environment in particular scenarios. An indicative list of exposure pathways for both internal and external exposures is given below:

For releases to atmosphere and surface waters during normal operation (typically, for nuclear power plants):

(a) Inhalation of radionuclides in an atmospheric plume (gases, aerosols);
(b) Inhalation of resuspended material.
(c) Ingestion of crops;
(d) Ingestion of animal food products (milk, meat, eggs);
(e) Ingestion of drinking water;
(f) Ingestion of aquatic food (freshwater or seawater fish, crustaceans, molluscs);
(g) Ingestion of forest food (wild mushroom, wild berries, game);
(h) Ingestion of breast milk or locally elaborated baby food;
(i) External exposure from radionuclides in an atmospheric plume;
(j) External exposure from radionuclides deposited on ground and surfaces;
(k) External exposure from radionuclides in water and sediments (i.e. from activities on shores, swimming and fishing); and

(l) Inadvertent ingestion of soil and sediments.

For releases to the sewerage system during normal operation (typically for hospitals with nuclear medicine departments):

(m) Inhalation of resuspended sewage sludge; and
(n) External exposure from radionuclides in sewage sludge.

In some facilities or activities, radiation sources could contribute to doses to the member of the public living in the close vicinity of the installations or working[23] on site. Additional pathways to be considered are:

(o) Direct irradiation from sources stored in the facility (i. e. from spent fuel or radioactive waste storages);
(p) Direct irradiation from sources used in the facility (i.e. from industrial irradiators); and
(q) Direct irradiation from the facility (i.e. from components of the facility like nuclear reactors or coolant systems).

5.26. Depending on the exposure scenarios and the site characteristics, not all the exposure pathways listed in the paragraphs above may need to be included in the assessment; the contribution of an exposure pathway to the overall dose depends on the radionuclides involved, the habit data, the occupation factors and other characteristics of the population being considered. Therefore some exposure pathways may be excluded from the assessment on the grounds that the doses associated with certain pathway are negligible.

5.27. In some circumstances, it may only be possible to calculate doses for very general categories of food using generic values. For example doses can only be calculated for ingestion of crops, without being able to specify which types of crops are likely to be consumed. However, if surveys have been made close to the site then it may be appropriate to use site specific values of the actual crops in the region as long as the site-specific values are representative.

Identification of representative person for normal operations

5.28. Dose should be calculated to a representative person[24] using characteristics selected from a group of individuals representative of those more highly exposed in the population. Ref. [42] gives guidance on the characteristics of the representative person.

5.29. The characteristics of the representative person should be defined by the applicant according to the national regulations and through a systematic review process involving the

[23] This refers to workers to whom the exposures are not considered occupational, which, for the purpose of the radiological impact assessment and control, are considered as members of the public.
[24] The concepts of reference person and representative persons are defined by ICRP for radiation protection purposes. Reference person is a nominal individual for whom the doses are calculated by averaging doses to a reference man and a reference woman [3]. GSR Part 3 [1] defines representative person as: An individual receiving a dose that is representative of the doses to the more highly exposed individuals in the population. Representative person or persons are not the actual members of the population but a reference individual defined using dosimetric models and habit data characteristic of those more highly exposed. The dose to the representative person is the equivalent of, and replaces, the mean dose in the 'critical group'. The concept of critical group remains valid.

regulator. For example, the regulatory body may require the use of more detailed and site specific habit data for assessments carried out for certain types of facilities or at later stages in the (regulatory) authorization process.

5.30. Habit data of the representative person should be habits typical of the population living in the region where the facility is located or of the country at large. Habit data used in an assessment can be obtained from statistics collected at national, regional or international level or, where possible, from surveys carried out at or near the location where the facility will operate. Habit data include, for example, consumption rates of food and drinking water and inhalation rates. Important characteristics when assessing doses to the representative person is the assumed location (e.g. distance and direction from the point of release), where they live, obtain their food, and the fraction of the food consumed that is of local origin, occupancy times (time spent at different locations) and time spent outdoors and indoors.

5.31. Account should be taken of factors reducing the level of exposure where people live, such as the degree of shielding or filtering offered by the buildings assumed to be inhabited. The position of the representative person can be based on an actual or a postulated person or group of persons in a conservative location from the point of view of the exposure (e.g. close to the fence or in the regions where the highest deposition of radionuclides in the ground can be expected).

Assessment of dose to representative person

5.32. The assessment of radiological impact to the public should be estimated using individual effective dose to the representative person, which is the sum of the committed effective dose from intakes of radionuclides (by ingestion and inhalation) and effective dose from external irradiation [1, 3]. Doses from internal irradiation are calculated using dose coefficients from intakes of radionuclides by ingestion and inhalation, which provide committed effective doses per unit activity of intake, expressed in units of Sv Bq^{-1}. Tabulated values of dose coefficients applicable for members of the public are available in a number of publications [1, 43]. For calculating effective dose from external irradiation, standard models exist as well as compilations of dose coefficients [1, 44].

5.33. Dose coefficients for internal irradiation are provided for different age groups [1, 43]. If there are factors that may result in a particular age group being the more highly exposed then this age group should be considered. The application of dose coefficients for age groups should be weighed in relation to the ability to predict concentrations in the environment from a source and the ability to account for uncertainties in habit data for individuals exposed. Uncertainties in estimates of dose, particularly for prospective calculations, are generally not reduced significantly by increasing the number of age categories for which dose coefficients have been provided [42].

Comparison of doses with constraint and limits

5.34. For the purpose of comparison with the dose estimations, the government or the regulatory body should define a dose constraint below the dose limits for members of the public, taking into accounts the requirements in GSR Part 3 [1]. IAEA provides guidance for the definition and use of dose constraint for protection of members of the public in planned exposures situations in [6].

5.35. GSR Part 3 [1] defines an annual effective dose limit of 1 mSv for members of the public. Dose constraints should fall within the range of 0.1–1 mSv [6] and could be different

for different facilities and activities or exposures scenarios. The government or the regulatory body may define a generic value for dose constraint for different activities or facilities [8]. The effective dose estimated using the sum of the doses from external exposure in the specified period and the relevant committed[25] doses from intakes in the same period should be used to compare with the constraint; the period for calculating the committed dose should be defined considering life expectancies, for example 50 years may be taken for intakes by adults and up to age 70 years for intakes by children.

5.36. Because dose constraints refer to a single source, the regulatory body should take account of the possible contribution to the individual doses of other sources, for example another installation located close by or in the same site.

5.37. At a governmental decision-making process or an early stage of a (regulatory) authorization process, the generic value of a dose constraint for different types of activities and facilities (i.e. for nuclear fuel cycle facilities) [6, 8], could be used for comparison with the results of the initial radiological environmental impact assessment. Later the results of the assessment should be compared with the specific dose constraint for the activity or facility under consideration, as defined by the regulatory body. Once the radioactive discharge limits for a facility or activity are set by the regulatory body, a dose corresponding to the authorized discharge limit could be used for comparison to the results of the assessment. The process of setting discharge limits is discussed in [8].

5.38. When considering transboundary impacts the criteria used for the assessment of the level of protection in other States should be in line with the criteria discussed in this safety guide and, in principle, may be the same used in the State where the facility or activity is located.

ASSESSMENT FOR PROTECTION OF THE PUBLIC AGAINST POTENTIAL EXPOSURES

5.39. Facilities and activities are designed, constructed, commissioned, operated or conducted, maintained and decommissioned —and regulated throughout all these stages, in such a way to prevent and mitigate accidents that, in the vast majority of cases, result in no radiological consequences for the public [1, 2, 45, 46].

5.40. During the safety assessments carried out for activities and facilities in accordance with the IAEA Safety Standards [1, 5], various types of accidents are postulated to identify engineered safety features and operating action to reduce their likelihood and, should they occur, mitigate their consequences. These safety assessment enables to analyse whether adequate defence in depth has been achieved and give insights on the probability of various accidents and the potential source terms (if any) for such events, taking into account the safety measures in place and their effectiveness. In order to assess prospectively the potential exposures to members of the public, as required in the IAEA Safety Standards [1, 2, 45], those accidents, with their probabilities, should be considered.

5.41. The following paragraphs 5.42 to 5.71 provide guidance which should be used to conduct the assessments of the potential exposures to members of the public, once the type

[25] The lifetime dose expected to result from an intake.

and characteristics of the accidents are defined as a result of a safety assessment considering the initiating events and the safety measures implemented in the facility or during the conduct of an activity.

Procedure of the assessment

5.42. The prospective assessment of potential exposures uses estimations of doses to members of the public resulting from conceivable accidents identified through safety analysis, or a measure of risk[26] based on the estimation of such doses. The elements of such assessment are given schematically in Figure 3. In general terms, the first step should be to identify the potential exposure scenarios[27], based on the safety assessment. Next, the related source terms, including quantities and relevant physical and chemical characteristics of the releases (i.e. those that determine behaviour in the environment), should be considered to make the input to environmental dispersion and transport. Environmental dispersion and transfer should then be estimated with relevant models, considering the defined environmental scenario (i.e. the meteorological and hydrological scenario). The relevant exposure pathways should then be identified. The exposed representative person for consideration of potential exposures should then be selected. Finally, the dose, or a measure of the risk of health effects, should be assessed and compared with the applicable established criteria.

Potential exposure scenarios

5.43. For facilities having a very small number of engineered safety features, the identification and selection of potential exposure scenarios generally involves the consideration of typical industrial accidents or similar events leading to environmental releases —such as fires and accidental spillages and other types of inadvertent unexpected releases— combined with conservative or simple safety analysis techniques to determine the associated source terms.

5.44. For facilities having many engineered safety features, thus necessitating complex assessments to determine the likelihood of events and the magnitude of the source terms, a greater number of potential exposure scenarios may need to be considered. For these assessments, complex safety assessment techniques may be necessary, combining deterministic and probabilistic methods and, in some cases, expert judgement.

[26] The concept of a measure of risk due to exposure to radiation resulting from conceivable accidents is discussed in Annex II.

[27] For the purposes of this Safety Guide, the expression ‘potential exposure scenarios’ is used to include the characteristics of all the events or sequences of events that may lead to an accident, including their source term characteristics and when applicable their frequencies or probabilities.

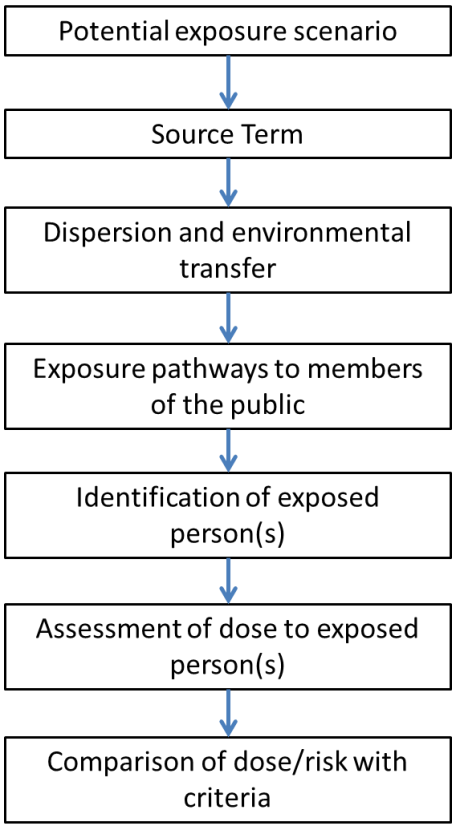

FIG. 3. Components of an assessment for consideration of potential exposures.

Source term

5.45. The types and amounts and the physical and chemical characteristics of radionuclides released during an accident may differ considerably from those for discharges in normal operation. Characteristic accidental source terms[28] should be estimated after considering the events or sequence of events leading to an accident and the safety measures aimed at limiting their magnitudes.

5.46. For nuclear facilities which have large inventories, complex engineered safety features and where the physical, chemical or nuclear characteristics may facilitate large releases in accident scenarios, detailed safety analysis techniques should always be applied to estimate more realistic potential source terms. Further guidance on accident source term estimations could be found in [47] and [48].

[28] Characteristic accidental source terms are those that can be considered to be a comprehensive representation of the characteristics of the specific facility or activity under accidental conditions. The accidental source terms identified as characteristics can be divided into different categories in accordance with their annual frequency or likelihood of occurrence and their magnitudes. Characteristic accidental source terms do not necessarily include the worst case scenario which tends to be an over-conservative assumption leading to estimations of unrealistic potential consequences. (For further information see Annex II).

5.47. In estimating source terms, consideration should be given to the physical and chemical processes occurring during the accident sequence, the behaviour of any safety feature or the effects of any mitigation measures, and the behaviour and movement of any radioactive material in the facility before it is released to the environment. A time profile for the release should be provided if needed. For example, in accidents at a nuclear power plant, initially noble gas radionuclides may be released to atmosphere followed then by volatile radioactive material and subsequently by other radioactive material in aerosol or particulate form. This time profile to the release may be taken into account by separating the source term into different phases.

5.48. As an indication, the source term should include the composition and amounts of radionuclides, the physical (e.g. gas or aerosol) and chemical form, the release point, the height (for an aerial release) or depth (for an aquatic release). The releases flow speed and the thermal energy associated with the release may be also necessary to assess the effective height the radioactive plume could reach.

Dispersion and environmental transfer

5.49. For activities and facilities needing simple assessments, conservative assumptions for the meteorological and hydrological data may be made. For example, a uniform wind direction for atmospheric dispersion and low atmospheric dilution conditions at the time of the postulated accident may be assumed. Such assumptions would give conservative results and avoid the need to obtain site specific data. However, conservative assumptions are not straightforward, e.g. assumptions conservative for inhalation (i.e. that all the releases go to the atmosphere instead of to any aquatic media) may be not conservative for ingestion of food produced with irrigation. When different pathways are involved, it might be not so easy to identify the most conservative assumption and a careful compromise should be evaluated.

5.50. If due to over conservatism, because of the use of assumptions which tend to largely overestimate the doses, the results are close to the selected criteria, more realistic values for the applicable meteorological and hydrological parameters at the location of the facility or activity should be considered to reduce the level of uncertainty. The meteorological and hydrological data are discussed in more detail in paragraphs 5.12 to 5.24 in the considerations of the dispersion and environmental transfer for normal operation.

5.51. For nuclear facilities or activities needing complex assessments , meteorological and hydrological data locally collected —over at least a year for the initial assessments, but preferable over 3–5 years— should be used to specify characteristic accident dispersion conditions [40, 41]. Site specific meteorological and hydrological data for nuclear facilities is generally collected during the programme for site evaluation; detailed guidance on the type and characteristics of this data is presented in [41]. If the data locally gathered for the prospective assessment of exposures during normal operation is not sufficiently comprehensive for accident analysis (for instance, if data on the long-range transport of radioactive material parameters in the atmosphere or in aquatic media are missing or if there is only monthly data) more detailed data (including hourly data if necessary) should be obtained from relevant regional records. Data could also be derived from the analysis of numerical atmospheric or aquatic models.

5.52. For nuclear facilities and others needing complex assessment, in order to reduce the calculation efforts, the hours of occurrence of the accident could be selected by means of statistical sampling techniques (such as cyclic or stratified sampling). Alternatively, an

assessment should be performed by using the full set of annual hourly meteorological data (in all cases, the resulting selected dispersion conditions have to be associated with a frequency of occurrence or a probability). For facilities needing simpler assessments, a single time or a small set of times for the occurrence of the release should be selected, and it should be ensured that the meteorological data for that time are conservative for the site under consideration.

5.53. Transfer models should be able to predict non-equilibrium conditions usually associated to accidental releases. In addition, there can also be significant short-term variations in the source term and meteorological conditions. If there is potential for a large release, models to estimate the transfer and the dispersion of radionuclides in the environment at longer distances (for instance, up to 100 km) should be available. Applicable dispersion models for short term releases and long range transport of radionuclides should be used when necessary to estimate the dispersion and distribution in the environment of radionuclides [11].

Exposure pathways to members of the public

5.54. The exposure pathways that are major contributors to the dose from accidental releases may be very different from those for normal operation. For example, consumption of fresh milk or vegetables immediately following an accident at a nuclear power plant could be an important pathway for exposures due to short lived iodine radionuclides. Care should therefore be taken in the adequate identification of the exposure pathways and in their modelling.

5.55. An indicative list of exposure pathways relevant for potential exposure scenarios which should be considered in the assessment is given below:

(a) External irradiation due to deposition on skin;
(b) External irradiation from the source;
(c) External irradiation from the plume;
(d) Inhalation from the plume;
(e) Inhalation of resuspended material;
(f) External irradiation due to deposition on the ground or other surfaces;
(g) Intakes of radionuclides due to the inadvertent ingestion of radioactive material deposited on ground or other surfaces; and
(h) Intakes of radionuclides due to the consumption of fresh and processed food and water.

5.56. Depending on the assumptions defined for the assessment, the exposure due to ingestion of contaminated food may be reduced or avoided due to the immediate implementation of protective actions. Other exposure pathways, such as inhalation and external irradiation, may also be significantly reduced if countermeasures are considered as hypothesis for the assessment. The exposure pathways and the assumptions of countermeasures should be clearly indicated and justified when reporting the results of the assessment.

Identification of representative person for potential exposures

5.57. A representative person[29] or persons, based on data from actual or postulated persons likely to be exposed in accident conditions should be identified for the consideration of potential exposures [49]; these may be different from those identified as representative persons for normal operation.

5.58. Different exposed population-groups may be identified, depending on the characteristics of the accident or event and the time of day or year of the postulated release, in accordance, for instance, with the prevailing meteorological or hydrological conditions, possible temporary occupation factors (i.e. different occupation during day and night, existence of summer campsites and schools, presence of workers near the facility) and seasonal effects in the habits and food products.

5.59. The end points[30] of the assessment of the potential exposures could change, depending on the type of the assessment and the criteria defined to consider potential exposures. For instance, instead of the concept of the person representative of those more highly exposed (representative person), a specific location (for example the nearest town in the region), fixed distances (for example, 1 km, 5 km or 10 km) or a distance where certain relevant projected dose is exceeded (for example, 10 mSv or 50 mSv —if such value is the threshold for protective measures) can be used. In some States specific individual persons or groups of persons are selected while in others the distribution of doses or risks among larger affected population is taken into account. Though there could be flexibility on the ways to consider potential exposures, and different States can adopt different options, the end points and the criteria should be clearly defined and justified, to avoid misunderstanding and misinterpretation of the results.

Assessment of dose to the representative persons for potential exposures

5.60. When considering potential exposures, mean absorbed doses to the organ or tissue, weighted by an appropriate relative biological effectiveness (RBE) for the biological end point of concern (for doses in the range for deterministic effects) and the effective dose (resulting from the sum of the committed effective dose from internal exposure pathways and the effective dose from external exposure, for doses in the range of stochastic effects) should be calculated. Equivalent dose to certain organs (e.g. thyroids) can also be used for consideration of potential exposures.

5.61. If the probabilities determined in the specification of the source term and in the meteorological distribution are analysed, the dose can be converted into an indication of the risk of health effects by means of risk coefficients provided, for example, by ICRP [50] (see Annex II for more details). The use of an indication of risk should be applied on the basis of national practices and regulations.

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[29] ICRP uses the term 'representative person' for the consideration of both normal and potential releases [42]. The 'representative person' for assessment and control of exposures for normal operation is defined in some national legislations or regulations of States; it is important to note that, despite the same name and general concept is applicable for both situations, the details and characteristic —like location, exposure pathways, time-occupation factors, age group— may be very different.

[30] IAEA Safety Glossary [4] defines 'end point' as a radiological or other measure of protection or safety that is the calculated result of an analysis or assessment. Common end points include estimates of dose or risk and predicted environmental concentrations of radionuclides.

5.62. Different age groups should be given due consideration when considering potential exposures, owing to the differences in the exposure conditions and in the associated radiation effects. The consideration of age groups should be carefully examined during the assessment. Experience has shown that infants are more exposed via some pathways, such as irradiation of the thyroid gland due to the incorporation of radioactive iodine isotopes, which could potentially be released in a nuclear reactor accident.

5.63. The relevant time periods over which exposures could occur and the relevant exposure pathways should be defined. For example, doses due to inhalation in the first 24 hours (mainly due to passage of the plume) or doses due to the ingestion of green vegetables over a three month period could be used as indicators of the main potential radiological impacts. In other cases, doses over longer periods could be estimated; for instance, from the time of an accident to one year afterwards. When comparing these with criteria, the time periods and exposure pathways under consideration should be clearly indicated in the results.

Comparison of dose/risk with criteria

5.64. GSR Part 3 [1] requires that the likelihood and magnitude of potential exposures be considered and that restrictions be established by the regulatory body[31]. For consideration of potential exposures—that uses as end points a dose or a measure of the risk of health effects— the restrictions established by the regulatory body should be in terms of a dose or risk criterion, as relevant.

5.65. For activities or facilities and activities needing a simple assessment and using a conservatively defined potential exposure scenario (i.e. installations with small inventories and sources with low capacity for accidental releases), a dose due to the defined conservative potential scenario is normally estimated and doses of 1 to a few mSv should be used as the decision criteria. For example, doses in the range of 1-5 mSv could be adopted as the range for establishing the criterion.

5.66. The International Nuclear Safety Group (INSAG) [51] and the ICRP [50] discussed possible risk criteria for potential exposure of members of the public which could be used by the regulatory body as the basis to define the national criteria. Ref. [51] states that for members of the public it seems to be appropriate that a risk for potential exposure, expressed as the annual probability of death attributable to a single installation[32], should not exceed 10^{-5}. Ref. [50] recommends that for the treatment of potential exposure, the risk constraint should be of the same order of magnitude as the health risk implied by the dose limits for normal releases exposures. Ref. [50] illustrates with a range of probabilities in a year which may be used to define risk constraints; for severe accidents with some deterministic consequences or when severe health effects are likely, the maximum probabilities should range from 10^{-6} to 10^{-5} per year. More detailed information on risk and criteria for consideration of potential exposures is provided in Appendix I and discussed in Annex II.

[31] Requirement 9 of GSR Part 3 (paragraph 3.15) [1] indicates that the number of affected people shall be assessed but this safety guide limit the scope to individual effects.

[32] Some sites could have multiple units and even multiple operators which, in some cases, could involve the same exposed persons and this would be considered when establishing the criteria.

5.67. The regulatory body should establish a risk constraint [1, 6] for the consideration of potential exposures; this could be based on INSAG [51] or ICRP [50] guidance. Some examples or risk criteria used by States can be found in Annex III. The definition and use of risk constraints are more discussed in [6].

5.68. When for a nuclear facility characteristic exposure scenarios are used to consider potential exposures, a dose corresponding to a potential exposure scenario or a reduced set of scenarios is normally estimated. In that case, the criteria should be defined in terms of dose. (for example a dose in the range 10-50 mSv related to the need of certain countermeasures could be used). Different values for the dose criteria could be defined within that range considering the different annual frequencies of those characteristics scenarios; i.e., for accidents with higher frequencies the dose criteria should be lower than for the accidents with very low frequency. Although the end point and the criteria of this type of assessment are in term of doses, owing to the fact that some frequencies are involved, there is an implicit notion of risk and the results can be related to the criteria discussed in Appendix I. This is more discussed in Annex III.

5.69. Another option may be to express the criteria qualitatively, in terms of 'a consequence to the public that would be unacceptable'. For instance, a criterion could be that very disruptive countermeasures —like large evacuation or relocation— as a result of the potential accident scenarios specified for the facility or activity would not be acceptable. Although this is in principle a qualitative criterion, the need of these countermeasures should be determined using estimations of projected doses (or related operational magnitudes) and comparing these estimations against emergency response decision numerical criteria. If this approach is used, the regulatory body should define the decision criteria for countermeasures to be used for the assessment of the potential exposures in line with the requirements in [18]. Examples of use of those decision criteria for countermeasures are available in [7].

5.70. Different criteria may be set for facilities and activities with varying levels of inventory and technological complexity. For instance, the regulatory body may specify one set of criteria for the nuclear fuel cycle and another set of criteria for hospitals or small laboratories.

5.71. When considering transboundary impacts the criteria used for the consideration of potential exposures in other States should be in line with the criteria discussed in this safety guide and, in principle, may be the same used in the State where the facility or activity is located.

CONSIDERATION OF THE ASSESSMENT OF THE PROTECTION OF THE ENVIRONMENT

5.72. The aim of radiological protection of the environment is set by the ICRP at a high level, for instance: to provide for the maintenance of biological diversity, to ensure the conservation of species and the health of natural habitats, communities and ecosystems [52]. Within IAEA Safety Standards, it is acknowledged that the general intent of the measures taken for the purposes of environmental protection is to protect ecosystems against radiation exposure that would have adverse consequences for populations of a species (as distinct from individual organisms) [2]. Considerations for radiological protection of the environment may vary between States and should be subject to the regulations and guidelines of the national competent authorities, including regulatory bodies.

5.73. States may consider that the assessment of the protection to members of the public during the normal operation of facilities or conduct of activities is sufficient to demonstrate protection of the environment as well. This position is based on the assumption that the assessment and control of the exposure to radiation of humans, leading to very low and localized increments of radiation levels in air, water and soils, provides appropriated protection of the environment. In that case the radiological environmental impact assessment does not need to include explicit consideration of additional specific components of the environment.

5.74. Other States may consider necessary to include, in the radiological environmental impacts assessments, for certain facilities and activities, the estimation and control of exposures to other components of the environment, for instance to flora and fauna. In all of the cases, the requirement of graded approach [1] should be considered, i.e. that the efforts in the assessment should be commensurate to the expected level of risk.

5.75. Considering the low radiological risk for populations of flora and fauna, that is expected during the normal operation of facilities and conduct of activities, the methods used for the assessment of the impact to flora and fauna should be practical and simple, based on the scientific knowledge of radiation effects and should not impose unnecessary burden to operators and regulators. ICRP [39, 52] provides a practical approach to assess and manage the effects on flora and fauna due to releases to the environment; this approach by ICRP is consistent with other equivalent approaches used in States [53–55].

5.76. For national or international frameworks which require the explicit consideration of the protection of flora and fauna[33], this Safety Guide presents, in Annex I, a methodology to assess the impact to flora and fauna for normal operation[34], based on the ICRP approach for protection of different ecosystems in the environment [52, 56].

6. VARIABILITY AND UNCERTAINTY IN THE RADIOLOGICAL ENVIRONMENTAL IMPACT ASSESSMENTS

6.1. Uncertainty reflects the state of knowledge about the system being investigated and relates to how accurately the doses or the risk can be estimated. The main sources of uncertainty arise from the incomplete knowledge of the exposure condition of the representative person and on the variability of model parameters. Variability includes both, variations in the transfer of radionuclides in the different environments and for the case of humans, variations in living habits among individuals within a group as e.g. the food intake and the time spent indoors and outdoors. When defining the methodology, including the criteria, the regulatory body or the applicants of the facility or activity, as appropriate, should consider the aspects related to variability and uncertainty (some aspects are discussed in the following paragraphs 6.2 to 6.10).

[33] For example, the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter 1972 (see: http://www.imo.org/OurWork/Environment/LCLP/Pages/default.aspx).

[34] Potential exposures to flora and fauna are not taken into account, since those are not amenable to regulatory control under accidental situations.

6.2. Sensitivity analyses techniques can be useful for identifying important parameters for determining the overall impacts and should be applied when possible. Such techniques include a systematic variation of the individual parameters or assumptions used in modelling, in order to determine their influence on the results of the assessment.

6.3. In general, an assessment provides a single result for each end point — for example, the dose to the representative person. This type of analysis is called deterministic analysis and is generally being based on reasonable conservative assumptions. For instance the assessment could use conservative assumption with regard to the exposure scenario and mean value for the model parameters. The distribution of the resulting doses can be estimated e.g. by means of statistical methods, as Monte Carlo calculations, using the frequency distributions of the model parameters as input for the dose assessment. Model uncertainties should be addressed properly to facilitate the decisions by the governmental agencies and the regulators and the communication with other interested parties such as the public.

6.4. The assessments as described in this Safety Guide tend to be conservative by nature, in order to avoid underestimating the impact to the public and the environment. If the doses calculated are small fractions of the dose constraints, simple conservative methodologies could be considered sufficient. When the doses estimated conservatively are closer to the criteria or the decisions to be made with respect to the technology could have a high impact on the level of investment, the regulatory body should decide whether more detailed methodologies, including, for instance, the use of site specific data, are necessary to increase the realism in the assessment.

6.5. The level of uncertainty in the assessments of facilities and activities for protection of the public and the environment should still ensure that the actual doses to members of the public do not exceed the dose limits set by the national regulatory body. Ref. [42] suggests that statistical methods and models could be used when assessing doses, noting that the parameter values and other data (habit data and dose coefficients) used in environmental models are usually represented by distributions, and provides examples on how these distributions can be chosen, as well as information on how to carry out calculations using these distributions and also on how to interpret the results. In general, for environmental parameters single recommended values in bibliography [13, 14, 57] or average measured values, when available, should be used.

6.6. For assessments using single values of habit data, high percentiles in some of the habit data distribution could be used (for instance, in particular food consumption rates); for assessments considering the distribution of the habit data, the resulting dose in the 95% percentile should be used to be compared with the established criteria.

6.7. The establishment of environmental monitoring programmes, once the installation is operating, would provide confidence that the predicted doses are reasonable and do not underestimate real doses.

6.8. If insufficient information or data is available then a conservative estimate should be used. However, it should be avoided to combine many conservative assumptions and arrive at a result for the impact that is grossly pessimistic because this may result in unrealistic consequences.

6.9. Addressing variability and uncertainty during the assessment of potential exposures is more complex. Reasons for this complexity include:

(a) Selection of potential exposures scenarios: The scenarios selected, including accidental source terms and environmental conditions at the time of the accident, may not be representative of what might actually happen.
(b) The probability or frequency of the scenarios: Conservative analysis seeks to avoid the issue by assuming certain bounding representative initiating events and system failures . If, for example, probabilistic safety analysis techniques are used to estimate accident frequencies, these frequencies are determined by combining many other frequencies and failure probabilities all with their own uncertainties.
(c) Unlike exposures resulting from normal releases, which usually occur more or less continuously and can be averaged over a year smoothing out fluctuations, exposures due to potential releases will usually be short and the impact will be dependent on actual conditions as e.g. the weather and the location of members of the public.
(d) Unlike the estimations of exposures resulting from normal releases, which can be validated retrospectively by means of the environmental monitoring programmes established during the operational stage, this is not possible for potential exposures.

6.10. Sensitivity studies could be carried out to determine how sensitive the overall result is to any source of uncertainty. The overall result could be sensitive to one or several parameters and assumptions on the underlying exposure scenario. Further research, modelling, or experimental data collection may need to be carried out, if the reduction of the level of uncertainty is deemed to be necessary.

APPENDIX I.
CRITERIA FOR CONSIDERATION IN THE ASSESSMENT OF POTENTIAL EXPOSURE TO THE PUBLIC

I.1. This Appendix presents criteria, as discussed by relevant international organizations, which could be used as guidance for regulatory bodies to define national criteria. The criteria discussed in this Appendix are for risk of health effects to individual members of the public. Other types of effects related to accidental situations with large releases to the environment, like social, economic and environmental implications, are out of the scope of this Safety Guide (as it was explained in Section 5).

I.2. Risks of health effects to members of the public may arise from potential exposures related to accidental releases of radioactivity. Annex II provides definitions and information on risk. International schemes which could be used to define national approaches for criteria for potential exposures are summarized and discussed below.

INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP

I.3. The International Nuclear Safety Advisory Group (INSAG) considered safety goals for potential exposure (INSAG 9) [51] making the following statements for individual risk to a member of the public:

> "It seems appropriate that for members of the public a risk for potential exposure, expressed as the annual probability of death attributable to a single installation, should not exceed 10^{-5}."
>
> "…it seems reasonable to expect that accidents that require simple, local countermeasures" [dose to most exposed member of the public of 10–100 mSv] "should have an annual probability of not more than about 10^{-4}."
>
> "An annual probability of such an accident" [more severe accidents with a dose to most exposed member of the public of 1 Sv] "of 10^{-5} is likely to be required because of the societal consequences."

I.4. For nuclear power plants, risk targets from INSAG 12 [58] are quoted: a severe core damage frequency of less than 10^{-4} events per year for existing nuclear power plants which with the application of all safety principles should be not more than 10^{-5} events per year for new nuclear power plants. Severe accident management and mitigation measures should reduce by a factor of at least ten the probability of major external radioactive releases requiring off-site response in the short term. It states that this would correspond to an individual risk of death for a member of the public of much less than 10^{-5} per plant operating year for existing and 10^{-6} for new plant.

INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

I.5. The International Commission on Radiological Protection (ICRP) has recommended that for the treatment of potential exposure, the risk limits should be of the same order of magnitude as the health risk implied by the dose limits for exposures [50]. It adds:

> "One procedure for applying source-related constraints is to express the probability of an event sequence as a function of the dose that will be delivered should the

sequence actually occur. Such a constraint would express the maximum probability that can be permitted from sequences exceeding a given magnitude of dose."

I.6. Such a scheme is proposed and is reproduced in Table 2. For complex systems, similar sequences should be grouped adding their probabilities and taking the worst consequence from any individual sequence to represent the group as a whole. ICRP states that the values in Table 2 are intended to illustrate the types of constraint that might be imposed based on experience taking into account the benefits derived from the particular practice. It adds that the values might also be imposed as tentative constraints in the absence of operating experience, subject to revision as experience is gained and in such cases the constraints may be regarded as upper bounds. ICRP emphasizes that these constraints refer to potential exposure of an individual.

TABLE 2. RANGE OF PROBABILITIES IN A YEAR FROM WHICH CONSTRAINT MAY BE SELECTED [50]

Impact	**Probability Range**
Sequences of events leading to doses treated as part of normal exposures	10^{-1} to 10^{-2}
Sequences of events leading to stochastic effects only but above dose limits	10^{-2} to 10^{-5}
Sequences of events leading to doses where some radiation effects are deterministic	10^{-5} to 10^{-6}
Sequences of events leading to doses where death is likely to result	$< 10^{-6}$

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

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ANNEX I. CONSIDERATIONS ON PROTECTION OF THE ENVIRONMENT FOR NORMAL OPERATION OF FACILITIES AND ACTIVITIES

I-1. This Annex presents a methodology proposed by IAEA to assess and control the radiation exposures to flora and fauna due to the releases during normal operation of activities and facilities. The IAEA proposal is based in ICRP approach for protection of the environment [I-1, I-2]; the Annex discusses the key aspects of ICRP approach and the basis for the proposal by IAEA.

I-2. As discussed in Section 5 of this Safety Guide, the assessment of the level of protection of members of the public is, in many instances, sufficient to provide for an adequate protection of the environment; the need of the explicit assessment of flora and fauna protection is subject to the national or international applicable regulations and depends on the characteristics of the installations and the environmental scenarios under consideration. The methodology described in this Annex should be used, if deemed necessary, as a complement of the assessment of exposures to humans described in Section 5 of this Safety Guide, within prospective radiological environmental impact assessments.

I-3. Normally, for activities or facilities requiring a simple radiological environmental impact assessment (i.e. installations with small inventories and sources with low capacity for releases; see related discussions in Section 4 and Section 5) the explicit consideration of exposures to flora and fauna is not necessary, on the basis that a significant radiological impact to the environment having effects on populations of flora and fauna is not foreseeable, owing to, for example, the limited radionuclides inventory in the sources of the facilities or their intrinsically safe characteristics.

I-4. For facilities and activities for which, in view of their characteristics, the need of a more complex radiological environmental impact assessment can be foresee —for example facilities like nuclear installations and activities like uranium mining and milling— the explicit consideration of the radiation exposure to flora and fauna may be deemed necessary by the government or the regulatory body, accordingly to national or international applicable regulations. The IAEA recommends for that cases the use of ICRP approach to assess and control the effects of radiation on flora and fauna [I-1, I-2], which is consistent and compatible with similar approaches used by some States [I-3 – I-5]. ICRP approach uses the concepts of ‘reference animals and plants’, ‘representative organism’ and criteria in the form of ‘derived consideration reference levels’. These concepts and criteria are discussed below.

THE KEY ASPECTS OF ICRP APPROACH FOR PROTECTION OF THE ENVIRONMENT

I-5. The ICRP recommends that the aims of environmental protection are to prevent or reduce the frequency of deleterious radiation effects on biota to a level where they would have a negligible impact on the maintenance of biological diversity, the conservation of species, or the health and status of natural habitats, communities, and ecosystems [I-1, I-2, I-6]. This is in line with the IAEA established fundamental principles that include a principle for protection of the environment which aims to protect ecosystems against radiation exposure that would have adverse consequences for populations of a species [I-7].

I-6. Due to the complexity in the interaction of different species, radiological effects on ecosystems exposed to very low increments of the levels of radiation in the environment are

very difficult to be modelled and predicted. However, conclusions on the radiological impacts on populations of species and ecosystems, which can be applied prospectively to manage radioactive sources in planned exposures situations, could be extrapolated from the assessment of the exposures of a reduced number of individual organisms of a species, used as a reference [I-6].

I-7. For this purpose, ICRP identified species that can be considered to be representative of marine, terrestrial and freshwater ecosystems[35] and have a wide geographical variation: the reference animals and plants[36] [I-1]. In selecting these species, ICRP pondered their potential use in a pragmatic manner (e.g., the existence of databases with sufficient information) and consideration was taken on which species would be more affected due to the exposure of internal and external radiation owing to the presence of activity concentration in the environmental media [I-1]. ICRP approach for protection of flora and fauna considers effects of radiation at the individual level which could have an impact in the structure of the population of a species (e.g. early mortality, some forms of morbidity, effects on reproduction, induction of chromosomal damage) [I-1, I-2].

I-8. ICRP defined criteria to assess and manage the radiological impact to flora and fauna in the form of derived consideration reference levels [I-1]. The derived consideration reference levels are a set of dose rate bands[37] within which there is some very low probability of deleterious effects of ionizing radiation to individuals of flora and fauna, which may have implications in the structures or populations. Detectable effects in some single individuals of a population would not necessarily have consequences for the population as a whole [I-1]. For very low increments of doses at the local level (as that resulting during normal operation of most of the facilities and activities), impacts at the level of population can hardly be observed [I-1]. Derived consideration reference level bands span an order of magnitude; for dose rates below the lower level of the bands, no effects have been observed (or no information on effects were reported) [I-1, I-2].

I-9. The derived consideration reference levels do not represent limits; they should be considered as points of reference to inform on the appropriate level of effort that should be expended on environmental protection, dependent on the overall management objectives, the actual fauna and flora present, and the numbers of individuals thus exposed [I-2].

I-10. Consistently with the concept of representative person, ICRP defined the concept of representative organisms[38]. The derived consideration reference levels apply to the representative organisms.

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[35] With regard to the need for reference models to represent typical farm animals for the purpose of their protection - primarily large mammals that live essentially in a human environment — it was considered that the use of humans was probably sufficient for such managed environmental or ecological situations [I-1].

[36] A reference animal or plant is a hypothetical entity, with the assumed basic biological characteristics of a particular type of animal or plant, as described to the generality of the taxonomic level of family, with defined anatomical, physiological, and life history properties that can be used for the purposes of relating exposures to dose, and dose to effects, for that type of living organism [I-1, I-2].

[37] Radiation quality factors, like those used for the assessment of exposure to humans (resulting in effective doses expressed in Sv) are not applied to assess exposure to biota; the key quantity for the exposure assessment of biota is the absorbed dose, which is defined as the amount of energy that is absorbed by a unit mass of tissue of an organ or organism, given in units of Joules per kilogram or Gray (Gy) [I-1]. Due to the consideration of different species of flora and fauna, with different life spans, it is convenient to express the criteria in terms of a dose rate, in Gy per day (or its adequate subunit, for instance mGy/d) [I-1,I-8].

[38] The representative organism is a particular species or group of organisms selected during a site specific assessment, taking account of their assumed location with respect to the source [I-2].

I-11. Because derived consideration reference levels are not defined as limits, the estimated doses could result within the band or even above the bands and the radiological situation can still be considered acceptable, taking into account different factors. Factors which should be considered when making decisions based on impacts to flora and fauna and the estimated doses are above the bands are: the size of the area where the dose rates are assessed to occur, the time period predicted for such dose rates, the need to comply with a specific legislation, the type of managerial interest, the presence of additional environmental stressors, whether or not the assessment is related to actual species or generalized to plants and animals types, the degree of precaution considered necessary [I-1].

THE IAEA PROPOSAL OF A GENERIC METHODOLOGY TO ASSESS PROTECTION OF THE ENVIRONMENT

I-12. For the case of a generic assessment, as described in this Annex, the IAEA indicates that the representative organism should be directly the ICRP reference animals and plants relevant for the specific major ecological scenarios (e.g. terrestrial, marine, freshwater), located in an area where the exposure conditions lead to the highest doses.

I-13. Accordingly with the concept of representative organisms (e.g those organisms representative of the flora and fauna more highly exposed [I-2]), the dose rate to be used in the assessment of the impact to populations of flora and fauna should not be the dose rate of the most exposed individual; the dose rate should be representative of the dose rates being received by a group of individuals located in the area where the highest exposures may occur.

I-14. To consider which is the area where the group of individuals representative of those more highly exposed are located, the typical spatial distribution of radionuclides in the environment should be considered. In general, activities and facilities in normal operation can be considered as point sources with steady-state or semi steady-state releases and, in most cases, the highest activity concentrations in air, soil, water and biota, averaged along the year, are normally found within the first kilometres from the sources. The activity concentrations in the environment decrease significantly with the distance from such highest concentrations. This typical behaviour of materials released from a point source to the environment is illustrated in Figure I-1, for atmospheric and aquatic dispersion.

I-15. Due to the annual distribution of wind directions and, in some cases, the directions of the water flows in rivers, lakes and oceans, it is reasonable to assume that the highest activity concentrations could be detected in any direction within a radius of up to 10 km. Therefore, a reference area of approximately 100–400 km^2 located around the release point is indicated by the IAEA for generic assessments as described in this Annex. The definition of this area around the source would ensure that highest environmental activity concentrations due to normal releases are found within that area and, consequently, the reference animals and plants within that area would normally receive the highest assumed radiation doses. The size of this recommended reference area is indicative and can be re-assessed for certain facilities or activities, different locations and environmental situations.

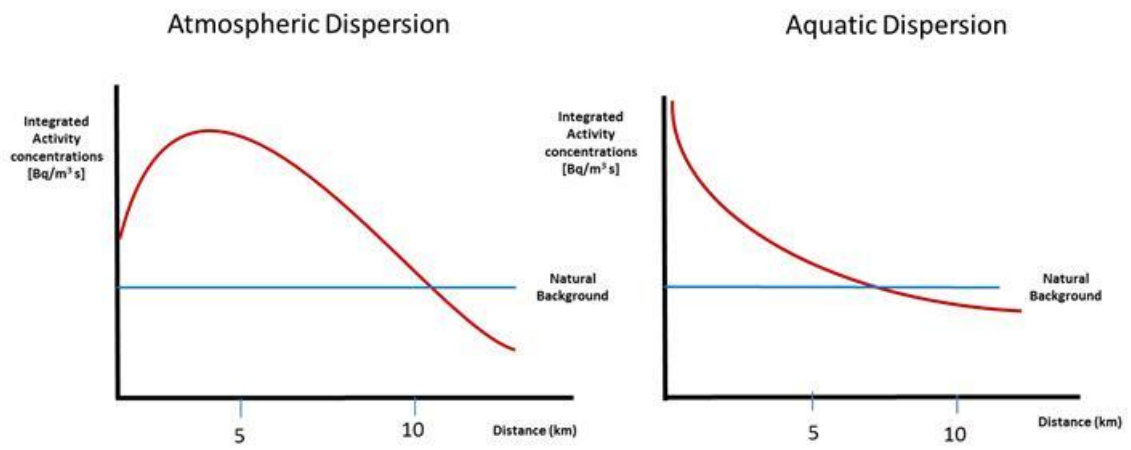

FIG. I-1. Typical patterns of environmental concentrations as a result of atmospheric and aquatic dispersion from a steady point source during normal releases from activities and facilities.

I-16. An area of 100-400 km^2 around the source, used to consider flora and fauna when performing radiological environmental impact assessments, is sufficiently large to ensure that mixing of the effluents with the environmental media occurs and that the number of individuals considered for the assessment is suitably large. This ensures that the estimated dose rates to be used in the assessments are not that of the most exposed individual but representative of that dose rates being received by the fraction of the population more highly exposed.

ASSESSMENT FOR PROTECTION OF FLORA AND FAUNA FOR NORMAL OPERATION

Procedure of the assessment

I-17. The radiological environmental impact assessment for protection of flora and fauna for normal operation uses estimations of the dose rates to flora and fauna resulting from the controlled releases resulting from the operation of facilities or conduct of activities. Figure I-2 gives schematically the components of such assessment. First, using the estimated source term for normal operations and environmental dispersion and transfer models, activity concentrations in a number of environmental media relevant for flora and fauna should be estimated; then, combining activity concentrations with dosimetric data as well as information on the times spent in different habitats (e.g. on or above soil, in the water or in aquatic sediments), dose rates from internal and external exposures to reference animals and plants representative of those more highly exposed relevant for the ecosystems under consideration should be estimated. Finally the resulting dose rates should be compared to the derived consideration reference levels.

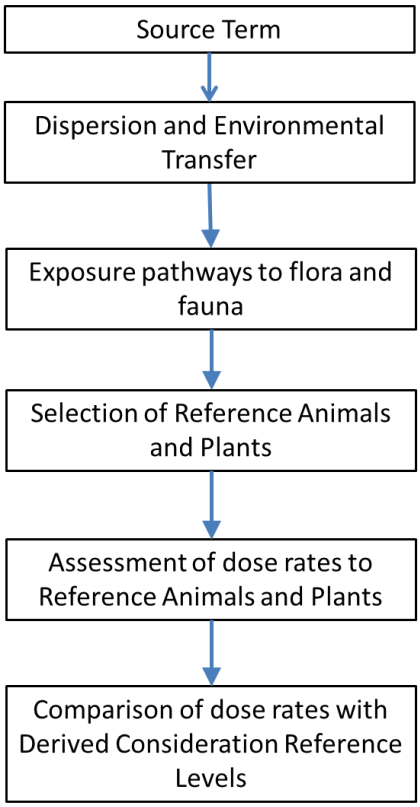

FIG. I-2. Components of an assessment for protection of flora and fauna for normal operations.

Source term and dispersion and environmental transfer

I-18. The characteristics of the source term and the models to simulate the dispersion and environmental transfers for flora and fauna (the first 2 boxes in Figure I-2) should be similar or the same to those described in the assessment of exposures to humans for normal operation in Section 5 in this Safety Guide, ensuring that the environmental media considered are relevant to estimate exposures to flora and fauna. For instance, the models should be able to predict the activity concentrations in the environmental media such as air, freshwater, seawater, aquatic sediments and soil, and the environmental transfer parameters should be the relevant for flora and fauna. IAEA provides models and data applicable for flora and fauna [I-9, I-10].

Exposure pathways

I-19. The exposure pathways that should be considered when assessing doses to flora and fauna [I-1] are:

(a) External exposure due to radioactive material in the atmosphere, water, soil and sediments; and
(b) Internal exposure from incorporated radioactive material.

Selection of the reference animals and plants

I-20. A generic assessment should use types of animals and plants for major ecosystems (terrestrial, freshwater and marine) which are relevant to the location being assessed [I-1]. These types of animals and plants for the different ecosystems and the related reference animals and plants defined by ICRP [I-1] are presented in Table I-1 below[39].

TABLE I-1. TYPES OF ANIMALS AND PLANTS FOR THREE MAJOR ECOSYSTEMS TO BE USED IN GENERIC ASSESSMENTS OF RADIOLOGICAL IMPACT TO FLORA AND FAUNA AND RELEVANT DERIVED CONSIDERATION REFERENCE LEVELS (DCRL) [I-1]

Ecosystem of interest	Types of animals and plants	ICRP reference animals and plants	DCRL [mGy d^{-1}]
Terrestrial	Large plant	Reference pine tree	0.1–1
	Small plant	Reference wild grass	1–10
	Insect	Reference bee	10–100
	Annelid	Reference earthworm	0.1–1
	Large mammal	Reference deer	0.1–1
	Small mammal	Reference rat	0.1–1
Freshwater	Aquatic Bird	Reference duck	0.1–1
	Amphibian	Reference frog	1–10
	Fish	Reference trout	1–10
Marine	Seaweed	Reference brown seaweed	1–10
	Crustacean	Reference crab	10–100
	Fish	Reference flatfish	1–10

I-21. In order to determine the exposure conditions of those animals and plants more highly exposed, the selected reference animals and plants should be located in a reference area around the source — normally around the release point — where the highest environmental activity concentrations will typically occur. The dose rates characteristic for this group should be estimated using, for example, the average activity concentrations within this reference area. Although ecological characteristics may vary, in general, areas surrounding the effluent release points in the order of 100–400 km^2 could be applied for most exposure scenarios relating to normal operation of activities or facilities[40].

Assessment of dose rates to representative animals and plants

I-22. Dose rates due to exposure via internal and external pathways should be calculated for the selected representative animals and plants located in the reference area around the source described before. The absorbed dose rate could generally be estimated by using environmental transfer models based on concentration factors medium to biota and the corresponding dosimetric factors for internal and external exposures. Ref. [I-10] and [I-11] provide environmental media to biota concentration ratios for different flora and fauna and Ref. [I-1]

[39] Ref. [I-4] provides an equivalent different set of reference organism.
[40] This area could be either a circle of about 5–10 km radius or a box of 10–20 km side, both centred at the release point.

provides dosimetric factors for the estimation of dose rates to the ICRP representative animals and plants[41].

Comparison of dose rates with reference levels

I-23. In a generic assessment as presented in this Annex, if the dose rates to the selected representative animals and plants are below the lower boundary of the relevant derived consideration reference level band, impact on population of flora and fauna could be considered negligible and the level of protection of environment can be considered adequate. In the case where the estimated dose rates are within the bands the situation can still be acceptable, but the regulatory body could decide whether additional considerations (i.e. improvement in the level of details of the assessment) or practical mitigation measures would be needed, bearing in mind that derived consideration reference levels are reference points, not limits. If the resulting dose rates are above the upper boundary of the relevant derived consideration reference level band, the regulatory body should decide if this implies a stronger need to consider more control on the source or further protection efforts. The derived consideration reference levels are presented in Table I-1 above[42].

DISCUSSION

I-24. The explicit consideration of the radiation exposures to flora and fauna in the radiological environmental impact assessments, in a manner commensurate with the level of risk, as described in this Annex, should be considered by States as an option to complement the environmental protection approach considering only human protection aspects which, ultimately, would reinforce the system of radiation protection.

I-25. The methodology presented in this Annex is of a generic character. For most facilities and activities and environmental situations, a generic assessment as described in this Annex would be sufficient to demonstrate the level of radiological protection of flora and fauna. However, a generic approach may not be appropriate for the assessment of the impact to flora and fauna in particular circumstances, for example when dealing with protected or endangered species or when very sensitive ecological niches are identified. For these later cases, a more specific assessment may be required.

I-26. The regulatory body or other competent governmental agency could identify specific environmental scenarios that need special considerations, different from those more of a generic character as presented in this Annex. The assumptions and types of assessments for situations needing special consideration should be discussed amongst those responsible for conducting the assessment, the national regulatory body and the competent governmental agency. In any case, the methods described in this Annex could be used as a screening tool for those particular circumstances.

[41] Ref. [I-9] provides practical methods to estimate dose rates to representative animals and plants using generic environmental dispersion scenarios and the dosimetric factors in Ref. [I-1].

[42] Some States have defined and used their own radiological criteria to assess radiological impact to flora and fauna which are compatible with the ICRP derived consideration reference levels [I-3 – I-5].

REFERENCES TO ANNEX I

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ANNEX II. CONSIDERATIONS ON RISK FOR THE ASSESSMENT OF POTENTIAL EXPOSURE OF THE PUBLIC

II-1. This annex refers to the assessment of potential exposures for protection of the public in the framework of prospective radiological environmental impact assessment.

II-2. The estimation of potential exposures requires the assessment and quantification of the impact of accidents or events that might happen with very low probability. Generally — and certainly in the case for nuclear installations — there will be a whole spectrum of possible potential exposure scenarios, ranging from those with little or no impact to those with a very high potential impact, the design and operation of the facility or conduct of activity being such that accidents with high impact have lower probability than events with minor impact.

II-3. A measure of risk due to the unplanned or accidental releases of radionuclides to the environment from some facilities and activities[43] is an important factor to be considered when assessing potential exposures. The risk due to potential exposures is controlled starting from the design of facilities and activities by provisions for protection and safety (e.g. defence in depth) that is commensurate with the likelihood and the magnitude of the potential exposures [II-1].

PROBABILITY OF HEALTH EFFECTS FOR PROSPECTIVE ASSESSMENTS

II-4. The estimation of radiation dose to the public resulting from postulated accidents, in terms of the effective doses[44], combined with a health-risk coefficient can be interpreted, in the framework of prospective assessment, as an indication of the probability that detrimental health effects will materialize. A generic health-risk coefficient for radiological stochastic effects on humans which can be used in prospective radiological environmental impact assessments is 5×10^{-2} Sv^{-1} [II-1].

DEFINITION OF A MEASURE OF RISK OF A CONCEIVABLE ACCIDENT

II-5. A term that is often introduced to express a combination of an impact of an event or scenario and the likelihood of that impact is ‘risk’. Various schemes have been developed to quantify its combination and thus, allow the risk or risks of various events to be directly compared. Confusion can arise between this term with a defined meaning and mathematical definition, and the everyday meaning of the word ‘risk’ which can be synonymous of hazard.

II-6. The BSS [II-1] defines ‘risk’ as “multi-attribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with actual or potential exposures”. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences.

II-7. As explained in the main text of this safety guide, when using a methodological approach for assessing prospectively the impact of potential exposures, for each potential

[43] A large number of facilities and activities have potential of only minor or negligible radiological consequences even under accident scenarios owing to very limited inventories or the intrinsically safe characteristics of the sources.

[44] IAEA Safety Glossary [II-2] defines effective dose equivalent as a measure of dose designed to reflect the risk associated with the dose, calculated as the weighted sum of the dose equivalents in the different tissues of the body. The definition of effective dose equivalent is superseded by effective dose.

exposure scenario, a consequence (e.g. a dose to representative person) and the associated probability of that consequence has to be determined.

II-8. For assessment for radiation protection purposes it could be useful to define a single mathematical definition of a measure of individual health risk[45] [II-3]. Since the consequence of a radiation dose can be expressed as the increased probability of health effects (for example death from early cancer)[46], an indication of the risk can be evaluated by combining the probability p of the scenario i occurring (p_i) and the probability of the health effects if it occurs (C_i).

$$R_i = p_i \times C_i \quad \text{(II-1)}$$

where R_i is the risk of health effect due to potential exposure scenario i.

II-9. If the events are mutually independent and the probabilities of the events are low, the risks of all the potential exposure scenarios could then be added to give the overall probability of health effect to the representative person:

$$R = \sum_i \ p_i \times C_i \quad \text{(II-2)}$$

II-10. As discussed in the previous paragraphs, the risk estimated within an assessment as described in this safety guide apply to an individual (the exposed person or representative person for potential exposures). For large facilities such as nuclear power plants which may potentially affect many individuals and which could cause other impacts as, e.g. evacuation and restriction of land use, possible societal risk could also need to be quantified and assessed against a criteria. However, the consideration of societal risk is not included in the present guidance and is subject to the national approaches.

II-11. Criteria which could be used for the consideration of risk resulting from potential exposures are presented in Appendix I of this Safety Guide, based on Refs. [II-4] and [II-5].

BASIC ASPECTS OF THE PROBABILISTIC ASESSMENT OF POTENTIAL EXPOSURES TO THE PUBLIC

II-12. As discussed in Section 5 of this safety Guide, for facilities having many engineered safety features, thus necessitating complex assessments to determine the likelihood of events and the magnitude of the source terms and the associated consequences, complex safety assessment techniques may be necessary, combining deterministic and probabilistic methods and, in some cases, expert judgement.

II-13. In a probabilistic assessment of potential exposures, frequencies of initiating events

[45] The definitions of 'risk' described in this Annex can only be interpreted as giving an indication of the risks, owing to the many uncertainties involved in a probabilistic safety analysis as it was described, in the estimation of the possible exposures and in the quantification of the associated radiological consequences.

[46] To be more precise, the probability of the health effect can be estimated using the dose response function, f(D), which changes with the level of dose. The risk of early health effects can also be calculated using hazard functions, taking into account the variation of risk with the rate at which dose is accumulated over a certain period (e.g. the first day or few days following the accident). The risk of late health effects can consider not only fatal but non-fatal cancers in different organs, leukaemia and heritable effects. The details of these considerations are out of the scope of this Annex which should be considered as introductory to the topic.

are estimated and the possible fault sequences (or a representative sub-set) that encompass the responses of plant and safety systems, including human operators, are determined. The overall probability or frequency of the fault sequence or scenario is calculated by combining the frequency of the initiating events with probabilities of each failure of event in the sequence. The use of probabilities and frequencies implies a definition of a period of time which can be selected arbitrary in order to perform the analysis. A period of one year is usually selected.

II-14. Then, the source term for each sequence is calculated. In some cases a reduced number of source terms encompassing similar source terms may be used for a set of fault sequences to reduce the calculation required.

II-15. The dose to the most exposed individual or individuals are then calculated by using a set of meteorological conditions and other environmental transfer conditions along with the probabilities of these conditions applying along with factors that affect the dose and their probabilities. For a given source term and target, one would need to include: for example, the probability that the wind was blowing from the source to the target, the probability of other meteorological conditions such as stability class, wind speed and rainfall, the probability that the person is outdoors or indoors, and so on. These probabilities are estimated based on the set of data for the location.

REFERENCES TO ANNEX II

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

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ANNEX III. EXAMPLES FROM STATES

EUROPEAN UTILITY REQUIREMENTS (LWR NUCLEAR POWER PLANTS ONLY) FOR NORMAL OPERATION AND ACCIDENT CONDITIONS

III-1. In 1991 the major European electricity producers formed an organization to develop the European Utility Requirement (EUR) document [III-1]. This document proposes a common set of utility requirements for the next generation of LWR nuclear power plants. Prior to these requirements, the development, design and licensing of existing LWR plants had been performed on a national basis with little interaction between countries.

III-2. The EUR document sets common safety targets which are consistent with the best European and international objectives. It states that these targets are values that are more restrictive than regulatory limits but are judged to be at a level that can be reasonably achieved by modern well-designed plants. Targets are set for normal operation, incident conditions, and accident conditions. For the preliminary design assessment, EUR has proposed criteria in terms of radionuclide releases rather than doses to members of the public. The targets are generally defined as linear combinations of the releases in each of the reference isotopic groups and depend on the category of the accident as determined by the estimated frequency of the initiating event. The detailed methodology can be found in [III-1].

APPROACH FOR POTENTIAL EXPOSURES IN THE UNITED KINGDOM

III-3. The United Kingdom nuclear safety regulator has issued Safety Assessment Principles which provides guidance to set numerical targets for potential exposures [III-2, III-3]. Table III-1 below summarizes the guidance on numerical targets applicable for off-site releases. These figures are termed basic safety levels which represent a level that it is considered a new facility should meet; basic safety objectives are set more stringent, for instance at lower levels (generally a factor of 100 lower) and mark the start of what is considered broadly acceptable. There are also targets for workers on-site.

TABLE III-1. NUMERICAL TARGETS FOR POTENTIAL EXPOSURES OFF-SITE IN THE UNITED KINGDOM

Target	**Applicability**	**Numerical values (Basic Safety Level)**	
Target 4	Design Basis fault sequences	1 mSv for initiating fault frequencies exceeding 1×10^{-3} pa 10 mSv for initiating fault frequencies between 1×10^{-3} and 1×10^{-4} pa 100 mSv for initiating fault frequencies less than 1×10^{-4} pa.	
Target 7	Individual risk of death from accidents	1×10^{-4} pa	
Target 8	Frequency-dose targets (all accidents)	Effective dose, mSv 0.1–1 1–10 10–100 100–1000 > 1000	Total predicted frequency pa 1 1×10^{-1} 1×10^{-2} 1×10^{-3} 1×10^{-4}
Target 9	Total risk of 100 or more fatalities (immediate or eventual)	1×10^{-5} pa	

APPROACH TO POTENTIAL EXPOSURES IN ARGENTINA

III-4. The Argentine Nuclear Regulatory Authority (ARN) has defined an Acceptability Criterion Curve (a function) against which the nuclear safety level of a nuclear power plant can be assessed [III-4 – III-6] (see Figure III-1 below). The criterion is based on the individual radiological risk limitation quantified in terms of probability and it is related to the dose limitation system recommended by the International Commission on Radiological Protection for protection against exposures to ionizing radiation resulting from normal operation [III-7].

III-5. The objective of the Acceptability Criterion is to limit the individual risk to members of the public associated with potential exposures that could originate from living in the proximity of a nuclear facility to values not greater than the individual risk associated with exposures from normal operations.

III-6. ICRP has suggested a risk coefficient for stochastic effects of 5×10^{-2} Sv^{-1} [III-7]. The ARN applies a dose constraint for exposure from a single source such as a nuclear power plant of 0.3 mSv per year and derive an annual limit value of the individual risk R, associated with exposures due to normal operation originating in a single practice or source of 1.5×10^{-5}.

III-7. For potential exposures the individual risk will be the sum of the risks associated with exposures from all possible accident sequences (a sequence is the series of events leading up to the radioactive release followed by a particular set of meteorological conditions or other exposure pathways that lead to exposure of an individual). The calculated risks do not take account of any counter-measures that might be implemented.

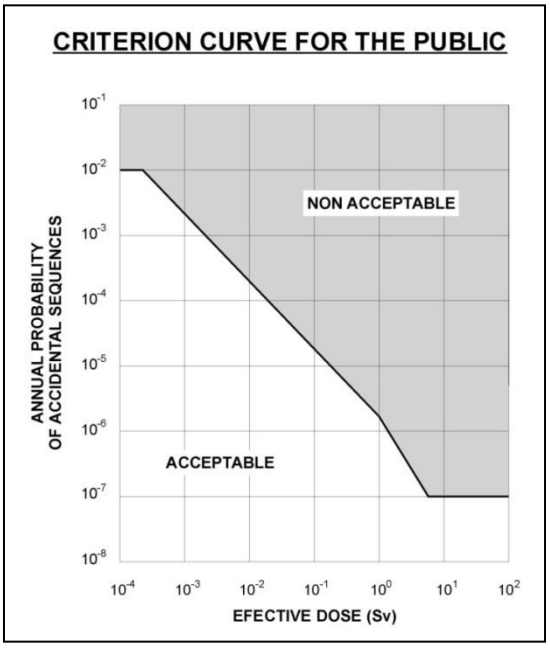

FIG. III-1. Argentine acceptability criterion curve for consideration of potential exposure of the public.

III-8. ARN recognizes that there are many uncertainties involved in probabilistic methods such as Probabilistic Safety Assessment (PSA) and to account for this a lower value (a factor of 15 lower) for the risk limit of 10^{-6} — in other words the individual risk of death from accidents at a nuclear facility for the most exposed individual must be less than 10^{-6} or 1 in a million.

III-9. Figure III-I (above) which is taken from the ARN Regulation [III-5] is a plot of the annual probability of accidental sequences against the effective dose resulting from all accidents with that annual probability showing the criterion curve.

APPROACH TO NORMAL AND ACCIDENT CONDITIONS IN THE USA

III-10. The United States Nuclear Regulatory Commission (NRC) is the Federal agency responsible for protecting the health and safety of the public and the environment by licensing and regulating civilian uses of source material, by-product material, and special nuclear material in medical, academic, research, and industrial applications (including the generation of nuclear power). The primary safety consideration in the operation of any nuclear reactor is the control and containment of radioactive material, under both normal operation and accident conditions. Numerous controls and barriers are installed in nuclear plants to protect workers and the public from the effects of radiation

III-11. The US National Environmental Policy Act of 1969, as amended (NEPA) directs that an environmental impact statement be prepared for major Federal actions that significantly affect the quality of the human environment. This includes considering other past, present, and reasonably foreseeable future actions that could potentially affect the same resources for both radiological and non-radiological effects. The NRC has implemented its NEPA obligations through 10 CFR Part 51. When reviewing an application for a nuclear plant, the NRC evaluates the potential exposures to the public due to radiological releases. In order to perform this analysis, the exposure pathways and receptor locations are determined. Receptor locations include areas having populations such as schools, hospitals, or residences, or they may be locations at which plants or animals that become food for the public may be exposed to either direct radiation or radionuclides contamination. Parameters necessary to determine the exposure pathways to calculate the dose include the population of the affected area (assumed to be within an 80 kilometre [50 mile] radius), the distance from the reactor to the receptor location, and the time required for the plume to reach the receptor locations.

III-12. The NRC analyses radiological consequences under normal conditions against the requirements of 10 CFR Part 20, “Standards for Protection Against Radiation. Effluent release limits are specified in 10 CFR Part 20, Appendix B. The NRC also has specified criteria under 10 CFR Part 50, Appendix I, to keep public dose from radioactive effluents as low as reasonable achievable (ALARA).

III-13. The NRC analyses design basis accident radiological consequences against the 10 CFR Part 100 and/or 10 CFR Part 50.67 dose criteria. The base guidance that the NRC provides for facilitating compliance with these criteria is contained in multiple NRC Regulatory Guides

SAFETY CRITERIA FOR EXPOSURES DUE TO NORMAL OPERATION AND POTENTIAL EXPOSURES IN SOUTH AFRICA

III-14. The elements of the Nuclear Regulatory Framework consists of legally binding requirements by International Safety Conventions, laws passed by Parliament that govern the

regulation of South Africa's nuclear industry, regulations, authorizations, conditions of authorizations, requirements and guidance documents that the National Nuclear Regulator (NNR) uses to regulate the industry. Requirements are developed in conjunction with the applicable authorized action and effectively cover all the relevant requirements on the holder, including those in legislation such as the Safety Standards and Regulatory Practices (SSRP). Guidance provides direction to the holder / applicant on how to meet the requirements set out in NNR's Regulations.

III-15. The NNR's policy for regulating radiation safety is in line with international consensus and requires that the risks to both the workforce involved in licensed activities and the public should not exceed prescribed limits for both normal operation and for potential accidents, and that both individual and population risks be maintained as low as reasonably achievable, social and environmental factors being taken into consideration. These fundamental principles lead to a system of radiation dose limitation for persons occupationally exposed to radiation and for members of the public.

III-16. Safety standards and regulatory practices adopted by NNR are in line with the IAEA and the International Commission on Radiation Protection as well as other international norms and standards such as INSAG, ASME etc. The suite of IAEA safety standards and the current IAEA basic safety standards in particular, were used as references in the development of the South African Regulations on Safety Standards and Regulatory Practices.

III-17. Increasing the level of safety culture within regulated entities is imperative towards achieving the high level of safety required by the NNR. In South Africa the SSRP regulation published under the National Nuclear Regulator Act, provides detailed technical rules to regulate the conduct of persons engaged in activities related to the use and exposure to fissionable materials, ionizing radiation and natural sources of radiation.

III-18. The SSRP regulation includes:

— Risk criteria which address the mortality risk from nuclear energy and radiation to the present and future generations;
— Acceptable radiation dose limits for exposure of people (individually and collectively) and the environment arising under normal operations and as a consequence of nuclear incidents;
— Fundamental safety principles to ensure that the activities relating to the construction, operation and decommissioning of facilities are conducted to achieve the highest standards of safety that can be reasonably achieved; and
— Emergency preparedness and response planning to mitigate the consequences of nuclear events and incidents.

III-19. The principal safety criteria refer to limits on the annual risk/dose to members of the public due to exposure to radioactive material as a result of accident conditions/normal operations.

III-20. In order to control the risk to members of the public due to accident conditions a limit of 10^{-7} fatalities per person per annum is established for all nuclear installations in South Africa. This figure is based on comparison with other risks imposed on society by industry and various natural disasters. Based on a projection of ten nuclear sites in South Africa during the operational lifetime of the existing nuclear installations, a factor of 0.1 is applied to this figure to obtain the risk limit of 10^{-8} fatalities per person per annum for each site. The risk to

the public is to be computed using projections on the relevant site-specific data (e.g. demographic, agricultural, farming practices, food consumption data).

III-21. A peak-to-average ratio of 50 is used to obtain an acceptable variation in risk in the country. This gives an upper risk limit for an individual of 5×10^{-6} fatalities per annum applicable cumulatively to all nuclear installations in the country.

III-22. Whereas for accident conditions the corresponding safety criteria relate directly to risk as determined using a probabilistic risk assessment methodology, the relevant criteria for normal operations refer directly to deterministic dose levels to the average representative of the critical group [III-8].

Table III-2 presents a summary of safety criteria related to normal operations and accident conditions.

CONSIDERATION OF POTENTIAL EXPOSURES FOR NUCLEAR FACILITIES IN FRANCE

(NOTE: It should be noted that there are ongoing discussion between the regulator (ASN) and licensee (EDF) with regard to dose for category 4 or DEC)

III-23. The article 3.7 of the 7th February 2012 decree on the General Rules for Nuclear Facilities prescribes that the nuclear safety demonstration should include radiological potential consequences of incidents and accidents. This assessment should include, for each scenario:

— The presentation of the assumptions considered for the calculation of the releases and for the exposure scenarios. The assumptions should be reasonably pessimistic for the calculation of the releases; the exposure scenarios should be based on realistic parameters, but should not take into account population protection countermeasures that authorities may implement.
— An assessment of effective doses received at short, intermediate and long terms, for several age classes as necessary; the equivalent dose to the thyroid should also be assessed for specific radioactive releases.
— An assessment of the potentially affected area.
— The kinetics of the consequences of the accident outside the nuclear site.

TABLE III-2. SAFETY CRITERIA RELATED TO NORMAL OPERATIONS AND ACCIDENT CONDITIONS FOR PUBLIC

Assessment Type	**Normal Operations**	**Accident Conditions**
	Deterministic	**Probabilistic**
Average Annual Population Risk	Risk to be controlled to a trivial level by application of the ALARA principle.	10^{-8} fatalities person^{-1} year^{-1} site^{-1} (one fatality per person per one hundred million year per site) (1)
Maximum Annual Individual Risk	250 μSv year^{-1} site^{-1} individual dose limit for the average representative of the critical group.	5×10^{-6} fatalities year^{-1} (one fatality per two hundred thousand year).

(1) Subject to a maximum of 10 nuclear installation sites in South Africa.

III-24. The dose assessments of an accidental release usually takes into account four pathways: external exposure to plume radiation, internal exposure due to inhalation of radioactive substances, ingestion of contaminated foodstuffs and external exposure to radiation from substances deposited on the ground. For nuclear power plants, the doses are assessed for adults, children and infants.

III-25. Typical dose assessments are carried out for short to long terms at several distances from the facility. For generic studies (no specific sites), following doses are assessed:

— Doses after 24h of exposure at 500 m (assumed to be typical distance of the fence from the facility);
— Doses after 7 days of exposure (2 km, 5 km, 10 km are typical distances); for power reactors, effective doses are assessed for example at 5 km and doses to the thyroid at 10 km;
— Doses after 1 year of exposure;
— Doses after 50 year of exposure (for adults only).

III-26. For specific site studies, the exact distance of the fence is used instead of 500 m and the exact distance of the first habitations instead of 2 km. In addition, areas where the contamination of foodstuff may exceed maximum permissible levels are assessed.

III-27. Neither countermeasures (for example, sheltering, soil decontamination) nor food restrictions are taken into account for all these assessments. The contamination of foodstuff is usually assessed with models based on dynamic processes involved in radionuclide transfers to vegetables and animal products. For specific site studies, site specific data are used for the dose assessment (e.g. local food consumption rates).

III-28. As a general rule for safety analysis, doses should be as low as reasonably achievable and should be less than appropriate national reference levels. For operating reactors, for the short term assessment (up to 7 days), operating conditions are specified by frequency of occurrence:

(a) for category 3 accidental conditions (10^{-2} to 10^{-4} y^{-1}), the effective doses are compared to 10 mSv (dose level for sheltering);
(b) for category 4 accidental conditions (10^{-4} to 10^{-6} y^{-1}), the effective doses are compared to 50 mSv (dose level for evacuation);
(c) for the operating conditions of the design extension condition, values for category 4 accidents are used.

III-29. In addition, short term doses to thyroid are compared to 50mSv (dose level for stable iodine administration).

REFERENCES TO ANNEX III

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[III-7] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 1990 Recommendations of the International Commission on Radiological Protection', ICRP 60, Pergamon Press (1991).

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