

IAEA Safety Standards

for protecting people and the environment

Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education

Safety Guide
No. WS-G-2.7



IAEA
International Atomic Energy Agency

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IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety, and also general safety (i.e. all these areas of safety). The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

Safety standards are coded according to their coverage: nuclear safety (NS), radiation safety (RS), transport safety (TS), waste safety (WS) and general safety (GS).

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The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at P.O. Box 100, A-1400 Vienna, Austria.

All users of IAEA safety standards are invited to inform the IAEA of experience in their use (e.g. as a basis for national regulations, for safety reviews and for training courses) for the purpose of ensuring that they continue to meet users' needs. Information may be provided via the IAEA Internet site or by post, as above, or by e-mail to Official.Mail@iaea.org.

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The IAEA provides for the application of the standards and, under the terms of Articles III and VIII.C of its Statute, makes available and fosters the exchange of information relating to peaceful nuclear activities and serves as an intermediary among its Member States for this purpose.

Reports on safety and protection in nuclear activities are issued in other publications series, in particular the **Safety Reports Series**. Safety Reports provide practical examples and detailed methods that can be used in support of the safety standards. Other IAEA series of safety related publications are the **Provision for the Application of Safety Standards Series**, the **Radiological Assessment Reports Series** and the International Nuclear Safety Group's **INSAG Series**. The IAEA also issues reports on radiological accidents and other special publications.

Safety related publications are also issued in the **Technical Reports Series**, the **IAEA-TECDOC Series**, the **Training Course Series** and the **IAEA Services Series**, and as **Practical Radiation Safety Manuals** and **Practical Radiation Technical Manuals**. Security related publications are issued in the **IAEA Nuclear Security Series**.

MANAGEMENT OF WASTE
FROM THE USE OF RADIOACTIVE MATERIAL
IN MEDICINE, INDUSTRY, AGRICULTURE,
RESEARCH AND EDUCATION

Safety standards survey

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

IAEA SAFETY STANDARDS SERIES No. WS-G-2.7

MANAGEMENT OF WASTE FROM THE USE OF RADIOACTIVE MATERIAL IN MEDICINE, INDUSTRY, AGRICULTURE, RESEARCH AND EDUCATION

SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2005

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FOREWORD

by Mohamed ElBaradei
Director General

The IAEA's Statute authorizes the Agency to establish safety standards to protect health and minimize danger to life and property — standards which the IAEA must use in its own operations, and which a State can apply by means of its regulatory provisions for nuclear and radiation safety. A comprehensive body of safety standards under regular review, together with the IAEA's assistance in their application, has become a key element in a global safety regime.

In the mid-1990s, a major overhaul of the IAEA's safety standards programme was initiated, with a revised oversight committee structure and a systematic approach to updating the entire corpus of standards. The new standards that have resulted are of a high calibre and reflect best practices in Member States. With the assistance of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its safety standards.

Safety standards are only effective, however, if they are properly applied in practice. The IAEA's safety services — which range in scope from engineering safety, operational safety, and radiation, transport and waste safety to regulatory matters and safety culture in organizations — assist Member States in applying the standards and appraise their effectiveness. These safety services enable valuable insights to be shared and I continue to urge all Member States to make use of them.

Regulating nuclear and radiation safety is a national responsibility, and many Member States have decided to adopt the IAEA's safety standards for use in their national regulations. For the Contracting Parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by designers, manufacturers and operators around the world to enhance nuclear and radiation safety in power generation, medicine, industry, agriculture, research and education.

The IAEA takes seriously the enduring challenge for users and regulators everywhere: that of ensuring a high level of safety in the use of nuclear materials and radiation sources around the world. Their continuing utilization for the benefit of humankind must be managed in a safe manner, and the IAEA safety standards are designed to facilitate the achievement of that goal.

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IAEA SAFETY STANDARDS

SAFETY THROUGH INTERNATIONAL STANDARDS

While safety is a national responsibility, international standards and approaches to safety promote consistency, help to provide assurance that nuclear and radiation related technologies are used safely, and facilitate international technical cooperation and trade.

The standards also provide support for States in meeting their international obligations. One general international obligation is that a State must not pursue activities that cause damage in another State. More specific obligations on Contracting States are set out in international safety related conventions. The internationally agreed IAEA safety standards provide the basis for States to demonstrate that they are meeting these obligations.

THE IAEA STANDARDS

The IAEA safety standards have a status derived from the IAEA's Statute, which authorizes the Agency to establish standards of safety for nuclear and radiation related facilities and activities and to provide for their application.

The safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment.

They are issued in the IAEA Safety Standards Series, which has three categories:

Safety Fundamentals

- Presenting the objectives, concepts and principles of protection and safety and providing the basis for the safety requirements.

Safety Requirements

- Establishing the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements, which are expressed as 'shall' statements, are governed by the objectives, concepts and principles of the Safety Fundamentals. If they are not met, measures must be taken to reach or restore the required level of safety. The Safety Requirements use regulatory language to enable them to be incorporated into national laws and regulations.

Safety Guides

- Providing recommendations and guidance on how to comply with the Safety Requirements. Recommendations in the Safety Guides are expressed as 'should' statements. It is recommended to take the measures stated or equivalent alternative measures. The Safety Guides present international good practices and increasingly they reflect best practices to

help users striving to achieve high levels of safety. Each Safety Requirements publication is supplemented by a number of Safety Guides, which can be used in developing national regulatory guides.

The IAEA safety standards need to be complemented by industry standards and must be implemented within appropriate national regulatory infrastructures to be fully effective. The IAEA produces a wide range of technical publications to help States in developing these national standards and infrastructures.

MAIN USERS OF THE STANDARDS

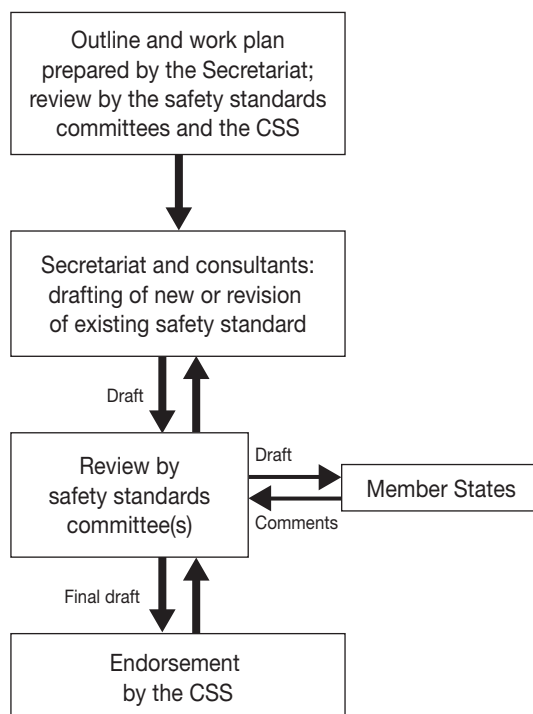
As well as by regulatory bodies and governmental departments, authorities and agencies, the standards are used by authorities and operating organizations in the nuclear industry; by organizations that design, manufacture and apply nuclear and radiation related technologies, including operating organizations of facilities of various types; by users and others involved with radiation and radioactive material in medicine, industry, agriculture, research and education; and by engineers, scientists, technicians and other specialists. The standards are used by the IAEA itself in its safety reviews and for developing education and training courses.

DEVELOPMENT PROCESS FOR THE STANDARDS

The preparation and review of safety standards involves the IAEA Secretariat and four safety standards committees for safety in the areas of nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS), which oversees the entire safety standards programme. All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the CSS is appointed by the Director General and includes senior government officials having responsibility for establishing national standards.

For Safety Fundamentals and Safety Requirements, the drafts endorsed by the Commission are submitted to the IAEA Board of Governors for approval for publication. Safety Guides are published on the approval of the Director General.

Through this process the standards come to represent a consensus view of the IAEA's Member States. The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the standards. Some standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the International



The process for developing a new safety standard or revising an existing one.

Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

The safety standards are kept up to date: five years after publication they are reviewed to determine whether revision is necessary.

APPLICATION AND SCOPE OF THE STANDARDS

The IAEA Statute makes the safety standards binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA. Any State wishing to enter into an agreement with the IAEA concerning any form of Agency assistance is required to comply with the requirements of the safety standards that pertain to the activities covered by the agreement.

International conventions also contain similar requirements to those in the safety standards, and make them binding on contracting parties. The Safety Fundamentals were used as the basis for the development of the Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. The Safety

Requirements on Preparedness and Response for a Nuclear or Radiological Emergency reflect the obligations on States under the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

The safety standards, incorporated into national legislation and regulations and supplemented by international conventions and detailed national requirements, establish a basis for protecting people and the environment. However, there will also be special aspects of safety that need to be assessed case by case at the national level. For example, many of the safety standards, particularly those addressing planning or design aspects of safety, are intended to apply primarily to new facilities and activities. The requirements and recommendations specified in the IAEA safety standards might not be fully met at some facilities built to earlier standards. The way in which the safety standards are to be applied to such facilities is a decision for individual States.

INTERPRETATION OF THE TEXT

The safety standards use the form 'shall' in establishing international consensus requirements, responsibilities and obligations. Many requirements are not addressed to a specific party, the implication being that the appropriate party or parties should be responsible for fulfilling them. Recommendations are expressed as 'should' statements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures) for complying with the requirements.

Safety related terms are to be interpreted as stated in the IAEA Safety Glossary (<http://www-ns.iaea.org/standards/safety-glossary.htm>). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard within the Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the main text (e.g. material that is subsidiary to or separate from the main text, is included in support of statements in the main text, or describes methods of calculation, experimental procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the standard. Material in an appendix has the same status as the main text and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. An annex is not an integral part of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material published in standards that is under other authorship may be presented in annexes. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

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1. INTRODUCTION

BACKGROUND

1.1. Radioactive waste is generated in a broad range of activities involving the use of radioactive material in medicine, industry, agriculture, research and education. The amounts of waste generated from these activities are often limited in volume and activity; however, they have to be managed as radioactive waste.

1.2. While the principles [1] and safety requirements [2] are the same for managing any amount of radioactive waste, a number of issues have to be considered specifically in organizations conducting activities in which only small amounts of waste are generated. This is the case in particular in respect of spent and disused sealed radioactive sources.¹ For activities involving the generation and management of small amounts of radioactive waste, the types of facilities concerned and the arrangements for waste management vary considerably. Furthermore, the types of radioactive waste differ from facility to facility. The safe management of small amounts of radioactive waste should therefore be given specific consideration.

1.3. The nature of the radioactive waste generated in the various activities under consideration also varies greatly. It may be in the form of discrete sealed or unsealed radiation sources or process materials or consumable materials. Waste arises as a result of many activities, including: diagnostic, therapeutic and research applications in medicine; process control and measurement in industry; and numerous uses of radioactive material in agriculture, geological exploration, construction and other fields. The radioactive waste under consideration can be in solid, liquid or gaseous form. Solid waste can include: spent or disused sealed sources; contaminated equipment, glassware, gloves and paper; and animal carcasses, excreta and other biological waste. Liquid waste can include: aqueous and organic solutions resulting from research and production processes; excreta; liquids arising from the decontamination of laboratory equipment or facilities; and liquids from activity measurement systems (such as those employing liquid scintillation counters). Gaseous waste

¹ Spent or disused sealed sources are not considered waste in certain States but the safe management of such sources is achieved by compliance with the requirements for radioactive waste, and as such they are included in this Safety Guide.

is generated at a number of facilities in the production and radiolabelling of chemical compounds and organisms and in the treatment of solid and liquid waste. A broader overview of waste arising from this range of applications is presented in Appendix I.

1.4. In view of the variable range of waste types encountered and the possibility of changes occurring in the ways in which the waste is generated and then managed, particular attention should be paid to the safety issues that may arise in their management and regulatory control. Regimes for both management and regulatory control should be sensitive and responsive to these factors.

1.5. In facilities in which only small amounts of waste are generated, there may be limited knowledge among the staff of the safety issues relating to radioactive waste management. The safety culture among the staff may not be particularly focused on radioactive waste management because of this limited knowledge and/or because insufficient emphasis is placed on the related issues by the operating organization.

1.6. Good operating practice can significantly reduce the amounts of radioactive waste generated but in general such waste cannot be entirely eliminated. The waste may contain sufficient quantities of radionuclides that it has the potential to present serious risks to human health and the environment if it is not managed properly. Experience has shown this to be the case in particular for spent or disused sealed radiation sources. Poor practices with such sources in the past have resulted in radiation exposure of both operating personnel and members of the public and have on occasion caused extensive contamination of the environment. There have been instances where lack of control over such sources resulted in considerable economic loss, serious health effects due to radiation exposure and even death [3–5].

1.7. This Safety Guide provides recommendations and guidance on the fulfilment of the safety requirements established in Ref. [2]. It covers the roles and responsibilities of different bodies involved in the predisposal management of radioactive waste and in the handling and processing of radioactive material. Other IAEA safety standards, in particular the Safety Guide on Predisposal Management of Low and Intermediate Level Waste [6], are also applicable where relevant.

OBJECTIVE

1.8. The objective of this Safety Guide is to provide recommendations and guidance on how to meet the objectives, principles and requirements established in Refs [1, 2] for the safety of radioactive waste management for waste arising from the use of radioactive material in medicine, industry, research, agriculture and education. It is intended for organizations generating and handling radioactive waste or handling such waste on a centralized basis and the regulatory body responsible for regulating such activities.

SCOPE

1.9. This Safety Guide is applicable to all activities involving radioactive waste, including spent and disused sealed sources, associated with the use of radioactive material in medicine, industry, research, agriculture and education. The Safety Guide covers waste generated in small to medium sized facilities such as nuclear medicine departments in hospitals and research centres, where waste is not usually generated in bulk. This includes waste generated from the use of radioactive material and waste generated by organizations carrying out decommissioning activities in such facilities. The Safety Guide covers the managerial, administrative and technical steps associated with the safe handling and management of radioactive waste, from its generation to its acceptance at a disposal facility or at a storage facility pending the availability of a suitable disposal option or its release from further regulatory control through a clearance mechanism. It does not specifically include detailed arrangements for the disposal of the waste. Requirements for the disposal of waste at near surface disposal facilities are established in Ref. [7].

1.10. The management of spent and disused sealed sources is emphasized in this Safety Guide because of the possibility of accidents having serious consequences.

1.11. This Safety Guide covers the safe management of radioactive waste generated at various facilities involving medical, industrial and research applications and at centralized national and/or regional facilities where radioactive waste may be collected and managed on behalf of a number of waste generators.

1.12. This Safety Guide is applicable to the management of limited quantities of waste containing naturally occurring radionuclides that arises from industrial

and research activities (such as the use of uranium in university laboratories or radium luminizing). Recommendations and guidance on the management of large quantities of radioactive waste arising from the mining and processing of ores are given in Ref. [8].

1.13. Guidance is provided on the storage of small amounts of radioactive waste at different stages of its management. Further details are to be given in a Safety Guide on the safe storage of radioactive waste.

1.14. This Safety Guide provides guidance on the transfer of radioactive waste from the premises of a waste generator to a centralized management facility for radioactive waste. Requirements for the transport of radioactive waste are established in Ref. [9] and related recommendations and advisory material are provided in Ref. [10].

1.15. Reference is made in this Safety Guide to the removal of regulatory control from radioactive material and to the control of discharges of effluents to the environment. Further details on such discharges are given in Ref. [11].

1.16. Where decommissioning produces only small amounts of waste, the guidance given in this Safety Guide is relevant. Recommendations on the management of waste arising from the decommissioning of medical, industrial and research facilities are provided in Ref. [12].

1.17. This Safety Guide provides guidance on safety assessment relevant to the management of radioactive waste that falls within its scope.

1.18. Hazards of a non-radiological nature are often associated with radioactive waste owing to the presence of other hazardous materials such as pathogens or heavy metals. Some guidance is given here on aspects to be considered with regard to these hazards, where these are related to radiation safety. In some cases these hazards will determine the choice of available waste management options. Recommendations concerning non-radiological hazards are outside the scope of this Safety Guide.

1.19. Consumer products such as smoke detectors used in homes that are exempted from the requirements of the Basic Safety Standards (BSS) [13] are outside the scope of this Safety Guide. If such products are collected for treatment and disposal as radioactive waste, the recommendations and guidance provided here are applicable.

STRUCTURE

1.20. Section 2 addresses the protection of human health and the environment in waste management. Section 3 describes the roles and responsibilities of the regulatory body, the users of radioactive material who generate radioactive waste (users) and the operators of waste management facilities (operators). Section 4 deals with general safety considerations. Section 5 outlines specific safety features in design and operation. Section 6 addresses aspects of waste disposal. Sections 7 and 8 deal with record keeping, reporting and management systems. Appendix I provides a general description of the waste arising from the production and use of sealed and unsealed sources and includes a list of the main radionuclides used in these activities. In cases where larger quantities of radioactive waste arise in association with the production of radiation sources, Ref. [6] is applicable. Appendix II presents an approach to safety assessment in the form of a fault schedule. Appendices III, IV and V provide typical management flow diagrams for solid radioactive waste, biological radioactive waste, and spent and disused sealed sources, respectively. Appendix VI gives typical examples of spent and disused sealed sources and techniques for their management. Appendix VII presents a strategy for the identification and location of spent and disused sealed sources.

2. PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT

GENERAL

2.1. The safety requirements established in Section 2 of Ref. [2] in respect of the protection of human health and the environment apply to the management of radioactive waste generated in medicine, industry, agriculture, research and education and other small uses. Radioactive waste is required to be managed in a manner that protects human health and the environment, now and in the future, without imposing undue burdens on future generations [1, 2]. The radiation exposure of workers involved in the management of radioactive waste is required to conform for normal operation to the system of dose limitation laid down in the BSS [13], and the risk of accidental exposure of workers is required to be controlled. Control is required to be exercised over the removal of radioactive material from controlled environments, the

discharge of effluents containing radionuclides, activities that may give rise to accidental releases, and the transport of radioactive waste in the public domain, so as to ensure compliance with the system of radiation dose limitation and optimization in relation to members of the public.

DOSE LIMITATION

2.2. The normal exposure of individuals, both workers and members of the public, is required to be restricted so that neither the total effective dose nor the total equivalent dose to relevant organs and tissues caused by the possible combination of exposures arising from authorized practices, including waste management, dealt with in this Safety Guide exceeds any relevant dose limit specified in Schedule II of the BSS [13].

OPTIMIZATION OF PROTECTION AND SAFETY

2.3. In relation to any source within a practice, it is required to optimize protection and safety so that the magnitude of individual doses, the number of persons exposed and the likelihood of exposure are all optimized, economic and social factors being taken into account, within the restriction that the doses to individuals delivered by the source be subject to dose constraints (Ref. [13], paras 2.24–2.26). Specifically, the choice of particular waste management options (including treatment, waste minimization, packaging and conditioning) should be optimized with any additional exposure to workers taken into consideration [6].

2.4. The process of optimization of protection and safety may range from intuitive qualitative analyses to quantitative analyses using decision aiding techniques, but is required to be sufficient to take all relevant factors into account in a coherent way so as to contribute to achieving the following objectives:

- “(a) to determine optimized protection and safety measures for the prevailing circumstances, with account taken of the available protection and safety options as well as the nature, magnitude and likelihood of exposures;
- “(b) to establish criteria, on the basis of the results of the optimization, for the restriction of the magnitudes of exposures and of their probabilities by means of measures for preventing accidents and mitigating their consequences” (Ref. [13], para. 2.25).

DOSE CONSTRAINTS

2.5. The optimization of protection and safety for any particular source or facility considered in this Safety Guide should be performed systematically for the entire practice, not simply within an individual activity, and should cover all activities involving radioactive material, including waste management. It should be demonstrated that individual doses would remain below established dose constraints, which should have regulatory approval. In establishing dose constraints, the regulatory body should take into consideration that:

- (a) Radiation protection for any persons who are exposed as a result of activities in the predisposal management of radioactive waste is required to be optimized, subject to dose constraints, and with the doses to individuals from all sources and activities kept within specified dose limits (Ref. [6], para. 2.2; Ref. [13], Section 2);
- (b) Such dose constraints should be established so as to ensure that the cumulative doses due to radioactive releases from all such activities do not exceed the relevant effective dose limit for doses to any member of the critical group. People distant from the source and future generations should also be taken into account.

CONTROL OF DISCHARGES AND CLEARANCE

Control of discharges of radioactive effluents to the environment

2.6. While the safe management of radioactive waste requires releases from the various waste management processes to be optimized, effluents may be released to the environment within authorized limits as a legitimate practice [1].

2.7. The Safety Fundamentals publication on The Principles of Radioactive Waste Management (Ref. [1], para. 308) states that:

“The preferred approach to radioactive waste management is concentration and containment of radionuclides rather than dilution and dispersion in the environment. However, as part of radioactive waste management, radioactive substances may be released within authorized limits as a legitimate practice into the air, water and soil, and also through the reuse of materials.”

The discharge to the environment of effluents containing small amounts of radioactive material, carried out in a controlled fashion, may be the most

reasonable option. The regulatory body should set limitations for the discharge to the environment of such effluents following the guidance provided in Ref. [11].

2.8. Reference [11] provides recommendations and guidance to the regulatory body on setting such limitations. The limitations on discharges should be such as to ensure that individual doses are within the dose constraints established by the regulatory body for the practice concerned. The limitations imposed should be such as to ensure that the annual dose to any member of the public is not greater than 300 μSv per year deriving from any single facility. If the possibility exists of there being several users of radioactive material or waste management facilities operating in the same area, the regulatory body may have to consider reducing the limitations on discharges to ensure that there is no possibility of an individual receiving doses deriving from several sources, giving rise to a combined dose that exceeds the relevant dose limit. By means of radiological assessment it should be demonstrated that the proposed discharges would not result in doses to the public that exceed these levels.

2.9. Specific regulatory limitations on discharges can be set for each individual case. Alternatively, regulatory limitations on discharges could be set on a generic basis by making conservative modelling assumptions. Generic assessments are likely to result in overestimates of radiological consequences in individual situations but may be more readily interpreted and followed by users and operators and more easily enforced. The regulatory body can provide assistance to users and operators in conducting their own assessments. However, this needs a much greater level of technical support by the regulatory body, which in many situations may not be warranted.

2.10. Users and operators should demonstrate compliance with the regulatory requirements for limitations on discharges by means of monitoring of releases and monitoring in the environment [11] or by means of calculations. The procedures and the measurement techniques for such monitoring or calculations should be subject to the approval of the regulatory body. Records should be kept of the results of such monitoring and calculation.

Clearance

2.11. The BSS require that:

“Sources, including substances, materials and objects [including waste], within notified or authorized practices may be released from further

requirements of the [Basic Safety] Standards subject to complying with clearance levels approved by the [regulatory body]. Such clearance levels shall take account of the exemption criteria specified in Schedule I [para. I-3: effective doses of the order of 10 μ Sv or less in a year; and either no more than about 1 man Sv collective effective dose committed by one year of the practice or an assessment that shows that exemption is the optimum option] and shall not be higher than the exemption levels specified in Schedule I or defined by the [regulatory body] on the basis of the criteria specified in Schedule I, unless otherwise approved by the [regulatory body]" (Ref. [13], para. 2.19).

2.12. The user or operator should have a formal mechanism in place to demonstrate compliance with regulatory requirements in respect of clearance (removing material from regulated areas). Additionally, there should be compliance with other requirements in respect of release from regulatory control regarding any other hazardous aspects of the waste (e.g. infectious or toxic properties).

2.13. Any radiation markings should be removed from any material to which regulatory controls no longer apply. Similarly radiation markings should be removed from containers containing material to which regulatory controls no longer apply, and markings should be removed from or covered on containers from which material subject to regulatory control has been removed, or empty, clean containers normally used for carrying or storing radioactive material.

2.14. Information on material from which regulatory control has been removed should be recorded and retained for examination by the regulatory body as required.

REMOVAL OF REGULATORY CONTROL FROM BUILDINGS AND SITES

2.15. When buildings and sites are decommissioned and before the removal of regulatory control, if appropriate, any residual radioactive waste should be properly managed, removed and transferred to an authorized storage or disposal facility. The facilities and sites should be decontaminated to the levels required by the regulatory body. Recommendations and guidance are provided in Ref. [12].

3. ROLES AND RESPONSIBILITIES

GENERAL

3.1. The management of all radioactive waste is required to take place within an appropriate national legal infrastructure that provides a clear allocation of responsibilities [1] and effective regulatory control of the facilities and activities concerned (Ref. [14]; Ref. [2], paras 3.5–3.9). The national legal infrastructure should also facilitate compliance with other national and international laws. Although laws are normally of general application, national legal systems may have facility specific or site specific regulations on the management of waste generated from particular activities. Requirements in respect of the responsibilities for establishing such an infrastructure and the responsibilities of the regulatory body for ensuring the safety of waste management are established in Refs [2, 14].

3.2. A national strategy for the management of radioactive waste should be developed in accordance with the safety objectives and principles [1]. A strategy is necessary in order to define the infrastructure and the means to be adopted for the management of radioactive waste. A key element in the strategy is the extent to which national or regional waste management facilities are developed rather than managing the waste at a number of locations, where it arises. There may be significant safety benefits to be obtained from the use of specialized national or regional waste management facilities. However, the decision should be made with account taken of, among other things, the quantities and types of waste generated and the expertise available and its distribution in the region or State. In the siting of a nationally or regionally designated facility or facilities for radioactive waste management, it may be appropriate to take advantage of facilities where larger amounts of radioactive waste are managed, such as national laboratories at which the necessary expertise is available.

3.3. In many of the situations covered by this Safety Guide, a strategy involving a combination of on-site and collective waste management in regional or national facilities is adopted. Thus waste containing short lived radionuclides may be dealt with locally at the site where it is generated and waste containing long lived radionuclides may be dealt with at a national and/or regional facility.

3.4. Thus waste management may involve operations carried out solely at the site where the waste is generated or it may involve the transfer of radioactive waste to a specified waste management facility. A specified facility, in particular a facility for the management of disused or spent sealed sources, may be in another State.

3.5. One aim of radioactive waste management should be to minimize waste generation and to produce waste in a form that conforms with the requirements for subsequent handling, processing, transport and storage, or that meets the acceptance requirements for disposal. The management option selected may also result in waste or material that is suitable for return to a manufacturer or supplier of radioactive material, to be recycled or discharged as liquids or gases to the environment under regulatory authorization [11], or for regulatory control to be removed from them as discrete entities.

3.6. The predisposal management of waste may involve the transfer of radioactive waste from one operator to another or the processing of waste in another State. The established legal infrastructure [14] should include provisions to ensure that there is a clear allocation of responsibility for safety during the entire predisposal management process for waste, including any transfer between operators. Consideration should also be given to the decommissioning of any facility at which waste is managed. This continuity of responsibility for safety should be ensured by means of appropriate authorizations by the regulatory body (for example, by means of a licence or a sequence of licences, in accordance with the national legal infrastructure and agreements among the States involved in the transboundary movement of waste).

3.7. Both regulatory and operational responsibilities for radioactive waste management should be clearly delineated and functionally separated as far as possible in order to ensure effective and strict regulatory control over the different steps in waste management and the organizations involved.

RESPONSIBILITIES OF THE REGULATORY BODY

3.8. The overall role of the regulatory body in relation to the safety of radioactive waste management is to establish safety standards and ensure compliance with these standards. The requirements for waste safety established in Ref. [14] can be fulfilled in a number of ways. It is appropriate for the regulatory body to provide national guidance on how these can be met. The

specific responsibilities placed on the regulatory body in relation to waste management are:

- (a) To review and assess applications from users and operators for the authorization of waste management activities and to establish conditions for authorization;
- (b) To issue, amend, suspend or revoke authorizations;
- (c) To conduct compliance assurance activities including inspections of the facilities in which waste arises and is managed;
- (d) To ensure that corrective actions are taken if unsafe or potentially unsafe conditions are detected;
- (e) To take the necessary enforcement action in the event of a violation of the regulatory requirements.

3.9. Further specific responsibilities [2, 14] placed on the regulatory body include:

- (a) To develop and update waste management regulations, safety principles and requirements;
- (b) To provide advice on development, interpretation and application of legislation;
- (c) To ensure that no activities generating radioactive waste commence without provision for proper management of the waste and that adequate and suitable storage capacity is available;
- (d) To ensure that an appropriate waste classification scheme is established with due consideration of national and international safety standards;
- (e) To ensure that standards and criteria relating to the safety of facilities, processes and operations for radioactive waste management are established, including handling, processing, transport, storage and disposal; these should address acceptance of waste packages for disposal in existing and planned facilities;
- (f) To ensure that responsibilities are assigned to appropriate parties who generate or manage radioactive waste for ensuring the preparation and retention of relevant documents and records covering all the steps in waste management, that the record keeping is carried out properly and that records are maintained for an appropriate period of time;
- (g) To establish safety standards for the decommissioning of facilities including conditions on the end points of decommissioning;
- (h) To establish standards for the removal of material from facilities or activities under regulatory control and to provide guidance on and obtain

appropriate regulatory approval for the authorized discharge of liquids and gases containing radionuclides;

- (i) To ensure that its own staff and those of users and operators have the necessary expertise and competence to perform their functions adequately and, where necessary, to ensure that adequate training is provided.

3.10. The regulatory body should require the user or the operator to submit safety documentation in support of an application for a licence or other type of authorization involving the management of radioactive waste. The safety documentation should include a safety assessment report commensurate with the complexity of the facility and, in relation to waste management, details of the following:

- (a) Chemical, physical and radiological properties of the waste to be generated;
- (b) A description of proposed radioactive waste management activities relating to waste generation (anticipated waste quantities, waste minimization and control), waste processing (pretreatment, treatment, conditioning, storage and transport), and a description of facilities and their associated systems;
- (c) A safety assessment of the facilities and thus a demonstration of the integrity of the facility and the associated measures for waste control;
- (d) Storage arrangements;
- (e) Arrangements for removal of regulatory control from material, activities and facilities, if permitted under the national regulations;
- (f) Arrangements for waste to be removed from the site for storage, treatment or disposal at some other site;
- (g) Discharge proposals (points and method of discharge and related controls);
- (h) Discharge and environmental monitoring programmes and safety assessment proposals;
- (i) Decommissioning plans and procedures;
- (j) Staff competence and training provisions;
- (k) A contingency plan in the event of an accident which involves radioactive waste.