IAEA
Atoms for Peace

IAEA SAFETY STANDARDS

for protecting people and the environment

Status: STEP 8
For Member States' review and submission of comments
Comments due by: 5 December 2014

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

DRAFT SAFETY GUIDE

DS454

IAEA
International Atomic Energy Agency

1. INTRODUCTION

BACKGROUND

1.1. Waste that contains or is contaminated with radionuclides arises from a number of activities involving the use of radioactive materials. Significant amounts of radioactive waste are generated from a broad range of activities involving medical, industrial and research applications of radioactive materials. The nature of this radioactive waste is likely to be such that radiation safety considerations must be taken into account for its safe management. The importance of the safe management of radioactive waste for the protection of human health and the environment has long been recognized, and considerable experience has been gained in this field.

1.2. Predisposal management of radioactive waste, as the term is used in this Safety Standard publication, covers all the steps in the management of radioactive waste from its generation up to disposal, including processing (pretreatment, treatment and conditioning), storage and transport.[1]

1.3. The general principles of managing radioactive waste in a safe manner have been set out in the Safety Fundamentals publication entitled Fundamental Safety Principles [2]. The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (Joint Convention) [25] is consistent with the Fundamental Safety Principles [2]. The present publication is concerned with the application of these principles to the management of radioactive waste prior to disposal. A brief description of the general approach to and the technical steps in the predisposal management of radioactive waste is given in the following paragraphs. Measures to prevent or restrict the generation of radioactive waste are put in place in the design of facilities and the planning of activities that have the potential to generate radioactive waste. Radioactive waste may be cleared from regulatory control if it meets clearance criteria, and effluents produced during operations may be discharged if authorized by the regulatory body. The reuse and recycling of material is sometimes carried out as a means of minimizing the amount of radioactive waste from an activity or facility. The remaining radioactive waste from all sources that is not cleared, discharged or reused needs to be managed safely over its entire lifetime, and there is, therefore, a need for the establishment of a national policy and strategy for the safe management of radioactive waste [3].

1.4. Processing of radioactive waste includes its pretreatment, treatment and conditioning and is primarily intended to produce a waste form that is compatible with the selected or anticipated disposal option. However, in many instances no disposal facilities are available and storage may be necessary for considerable periods of time before disposal facilities become available. Radioactive waste will also be handled and may be stored between and within the basic steps in its management and will also have to be in a form that is suitable for such handling and storage as well as for any transport.

1.5. Whilst the safety principles [2] and requirements [3] are the same for managing any amount of radioactive waste, there are a certain number of issues that have to be considered specifically within organizations generating only small amounts of waste. This is particularly so in respect of spent and disused sealed radioactive sources[2]. In activities involving the generation and management of small amounts of radioactive waste, there is variation in the types of facilities and in the arrangements for waste management. Furthermore, the types of radioactive waste differ from facility to facility. Thus, the approach to the safe management of small amounts of radioactive waste needs specific consideration.

1.6. The radioactive waste in such facilities is varied and may be in the form of discrete sealed or unsealed radiation sources or may be in the form of process 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 in many uses in research, teaching, agriculture, geological exploration, construction and other fields of human endeavour. The waste can be in solid, liquid or gaseous forms. Solid waste can include spent or disused sealed sources; contaminated equipment, glassware, gloves, paper; animal carcasses, excreta and other biological waste. Liquid waste can include aqueous and organic solutions resulting from research and production processes, excreta, liquids from the decontamination of laboratory equipment or facilities, and liquids from activity measurement systems (such as scintillation counting). Gaseous waste is generated at a number of facilities from the production and radiolabelling of chemical compounds and organisms and from the treatment of solid and liquid waste. A broader overview of waste arising from this range of applications is presented in Appendix I.

1.7. In view of the variable range of waste types encountered and the possibility for changes to occur in the ways in which they are generated and then managed, particular attention has to be given to the safety issues which may arise in their management and regulatory control. Both management and regulatory control regimes should be sensitive and responsive to these factors.

1.8. In facilities where only small amounts of waste are generated there may be limited knowledge among the staff about the safety of radioactive waste management. The safety culture in staff may not

---

[1] 'Predisposal' is a contraction of 'pre-disposal'; it is not a form of disposal. Terminology used in this publication is defined and explained in the IAEA Safety Glossary [1]. See http://www-ns.iaea.org/standards/safety-glossary.htm.

be particularly focused to radioactive waste management either due to this limited knowledge and/or because insufficient importance is given to the related issues by the organization.

1.9. Good operating practice can significantly reduce the amount of radioactive waste generated but in general, waste cannot be fully eliminated. The waste may contain sufficient quantities of radionuclides that if not properly managed the waste has the potential to present serious risks to human health and the environment. Experience has shown this to be the case and particularly in respect of spent or disused sealed radiation sources where poor practices 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. Instances have arisen where such lack of control has resulted in radiation burns, death and considerable economic loss.

1.10. It may be that not all processing steps are necessary for particular types of radioactive waste. The type of processing necessary depends on the particular type of waste, its form and characteristics, and the overall approach to its management, including consideration of the generation of secondary waste. Where appropriate, the waste material resulting from processing may be reused or recycled, or cleared from regulatory control in accordance with the regulations in place.

1.11. In some instances there are several potentially conflicting demands in the predisposal management of the waste that need detailed consideration to determine the optimal integrated solution. Such considerations include the balancing of exposures of workers and/or those of members of the public, the short term and long term risk implications of different waste management strategies, the technological options available and the costs.

1.12. To select the most appropriate type of pretreatment, treatment and conditioning for the radioactive waste when no disposal facility has been established, assumptions have to be made about the likely disposal option. It is necessary to address the interdependences and the potential conflicts between the operational demands of each of the various steps in waste management, while ensuring that the waste is contained and stored in a passive, safe condition. In striking a balance between choosing an option and retaining flexibility, it is necessary to ensure that conflicts between operational demands that might compromise safety are avoided [2].

1.13. This Safety Guide provides guidance on application of the safety requirements [3]. It addresses the roles and responsibilities of different bodies involved in predisposal management of radioactive waste generated in medicine, research and industry [4], in the handling and processing of radioactive materials and are supported by other relevant publications in the IAEA Safety Standards Series. This

[2] Spent or disused sealed sources are not considered waste in some States; however, the safe management of such sources entails meeting the requirements for radioactive waste, and as such they will be considered in this Safety Requirements publication.

publication supersedes 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".

OBJECTIVE

1.14. The objective of this Safety Guide is to provide guidance on how to meet requirements established in Refs. [3, 4, 6] on the safe management of radioactive waste arising from the use of radioactive materials in medicine, industry, agriculture, research and education.". The guidance is intended for organizations generating and managing radioactive waste, organizations handling such waste on a centralized basis and regulatory bodies responsible for regulating such activities. The document focuses on moderate sized facilities, like in medicine, industry and research, but can be applied to facilities with small inventories using a graded approach.

SCOPE

1.15. This Safety Guide is applicable to all activities involving radioactive waste associated with the use of radioactive materials including disused sealed radioactive sources (DSRS). The Safety Guide is generally focused on waste generated from small to moderate sized facilities, for example, hospitals and research centres, where waste is not usually generated in bulk quantities. It includes waste generated from the use of radioactive material and from organizations carrying out decommissioning activities in such facilities. The Safety Guide covers the managerial, administrative and technical issues associated with the safe management of radioactive waste, from generation to release from further regulatory control or its acceptance at a disposal facility or a storage facility awaiting the availability of a suitable disposal option. It does not specifically include detailed arrangements for disposal of the waste; safety requirements on disposal are given in Ref. [7].

1.16. The management of spent and disused sealed sources considered as radioactive waste is highlighted in the Safety Guide because of the propensity for accidents having serious consequences with such sources. Further guidance on safety and security of radioactive sources is given in . Therefore, we suggest adding the following two references: The IAEA Code of Conduct on the Safety and Security of Radioactive Sources (2004); IAEA RS-G-1.10 "Safety of Radioactive Generators and Sealed Radioactive Sources," (2006)

1.17. The predisposal management of radioactive waste may take place in the facilities where they are originated or in separate, dedicated waste management facilities or within larger facilities operated for other purposes, such as nuclear power plants or spent fuel reprocessing plants. In this publication, the term 'facility' is used to refer to any of these possibilities.

1.18. This Safety Guide covers the safe management of radioactive waste generated at facilities involving medical, industrial and research applications and at national and/or regional facilities where such waste may be collected and managed on behalf of a number of waste generators. This Safety Guide does not cover the safe predisposal management of radioactive waste generated at nuclear fuel cycle research and development facilities.

1.19. This Safety Guide is applicable to the management of limited quantities of waste containing naturally occurring radionuclides from industrial and research activities, (such as the use of uranium in universities or radium luminizing). The management of larger quantities of such waste from mining and milling of ores is addressed in another Safety Guide [8].

1.20. Specific guidance on the storage of small amounts of radioactive waste in different stages of its management is given in this Safety Guide. More detail on this issue is provided in a separate Safety Guide on storage of radioactive waste [9].

1.21. This Safety Guide provides general guidance on the transfer of radioactive waste from the premises of a generator to a centralized radioactive waste management facility. Detailed requirements and guidance on the transport of such waste can be found in Refs [10, 11].

1.22. Reference is made in this Safety Guide to removal of regulatory control from materials and to the control of effluent discharges into the environment. Further details on these matters are given in other documents [6, 12, 19].

1.23. Where decommissioning produces only small amounts of waste, the guidance in this Safety Guide is relevant. Further requirements and guidance on management of decommissioning waste are provided in Ref. [13, 14].

1.24. This Safety Guide provides guidance on safety assessment relevant to the management of the radioactive waste falling within the scope of the document. More detailed guidance on the safety case and safety assessment for the predisposal management of radioactive waste is given in Ref. [15].

1.25. There are often hazards of a non-radiological nature associated with radioactive waste due to the presence of other hazardous materials such as pathogens, heavy metals etc. Some guidance is given on aspects to be considered in respect of these hazards, where this is related to radiation safety. In some cases these hazards dominate the choice of available waste management options. Detailed recommendations regarding non-radiological hazards are beyond the scope of this Safety Guide.

1.26. The management of consumer products, such as ionization chambers, smoke detectors, gaseous tritium light devices and lightning rods frequently which are used in and on homes and other buildings and which are exempted from the requirements of the Basic Safety Standards [6] is outside the scope of this Safety Guide. Guidance on their management is provided in Ref. [36]. However, many States place restrictions on the available disposal options for certain types of consumer product, in order to minimize the amount of radionuclides present in the environment and not under proper control, to encourage recycling or in response to other regulatory controls. If, at the end of their useful lifetimes, consumer products are collected for disposal as radioactive waste, the guidance provided in this Safety Guide applies.

1.27. The document captures all types of guidance, much of which is contained in other documents, and which is applicable to all types of authorized activities. While the goal of having a consolidated guide for those who pursue predisposal processing of waste is laudable, there should be a note that clearly indicates that this type of activity should be integrated with all of the activities of a registrant or licensee. It is not the intent that separate records, management systems, radiation protection, etc. are used in this one area. All should be integrated in the licensee's organization.

STRUCTURE

1.28. Section 2 addresses protection of human health and the environment associated with waste management. Section 3 describes the roles and responsibilities of the regulatory body, users of radioactive material who generate radioactive waste and operators[3] of waste management facilities. Section 4 deals with steps in management of radioactive waste. Section 5 outlines safety case and safety assessment. Section 6 addresses development and operation of facilities and activities. Section 7 deals with management system, record keeping and reporting. Appendix I provides a general description of the waste arising from the production and use of sealed and unsealed sources in medicine, industry and research and includes a list of the main radionuclides used in these activities. Appendix II presents an example of a Fault schedule to safety assessment in the form of a Fault schedule for safety assessment. Appendices III, IV and V provide examples of management flow diagrams for solid, biological radioactive waste and spent and disused sealed sources, respectively. Annex I gives examples of spent and disused sealed sources and techniques for their management. Annex II presents an example of a strategy for identification and location of spent and disused sealed sources.

2. PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT

RADIOACTIVE WASTE MANAGEMENT

2.1. The safety objective and the fundamental safety principles established in Ref. [2] apply for all facilities and activities in which radioactive waste is generated or managed, and for the entire lifetime of facilities, including planning, siting, design, manufacturing, construction, commissioning,

---

[3] Generators of radioactive waste, including organizations carrying out decommissioning activities, and the operators of predisposal radioactive waste management facilities are considered to be engaged in the management of radioactive waste. In this Safety Requirements publication they are hereinafter referred to as 'operator(s)'.

operation, shutdown and decommissioning. This includes the associated transport of radioactive material and the management of radioactive waste.

2.2. The main options for the management of radioactive waste are presented in Section 4. To meet the safety objective, in considering options for the management of radioactive waste, due consideration has to be given to the protection of workers, the public (including future generations) and the environment.

2.3. References [3, 4, 27] require both the regulatory body and the operator to establish a management system that addresses safety, health, environmental, security, quality and economic requirements in an integrated manner. A key component of such a system in each organization is a robust safety culture.

2.4. In controlling the radiological and non-radiological hazards associated with radioactive waste, the following aspects must also be considered: conventional health and safety issues, radiation risks that may transcend national borders, and the potential impacts and burdens on future generations arising from long periods of storage of radioactive waste [6].

2.5. The safety requirements established in [3, 6] in respect of the protection of human health and the environment apply to the predisposal management of radioactive waste generated in medicine, industry and research and other small uses. Waste needs to be managed so as to protect human health and the environment now and in the future, without imposing undue burdens on future generations. This means that radiation exposure of workers involved in the management of radioactive waste should be optimized and under normal operational circumstances be in conformance with the system of dose limitation laid down in the International Basic Safety Standards [6] and that the risk of accidental exposure to workers need to be controlled. Public exposures which may arise from materials removed from controlled environments, from the discharge of effluents containing radionuclides, from accidental releases and from transporting radioactive waste in the public domain have also to be controlled to ensure compliance with the system of radiation dose limitation and optimization relevant to members of the general public.

GRADED APPROACH

2.6. The regulatory body has to consider a graded approach to the application of the requirements for the predisposal management of radioactive waste, depending on the hazards, the complexity of facilities and activities, and the characteristics of the waste, and will have to apply the requirements as necessary and appropriate. ([3], para. 1.16)

2.7. A graded approach is a process by which the level of analysis, documentation and actions necessary to comply with the safety requirements are commensurate with the factors below.

2.8. The graded approach should be applied in a way that does not compromise safety and ensures compliance with all relevant safety requirements and criteria.

2.9. The application of the graded approach in the context of medical, industrial, agricultural, research and educational facilities should take into account the factors, such as:

(a) Hazards and complexity associated with the facility and operation (processing including pretreatment, treatment and conditioning, and storage);

(b) Inventory, characteristics (radiological, physical, chemical and biological characteristics) ([26], Annex II, Table II-1) and criticality;

(c) Aspect of security (i.e., threat, the nature of the sources, and attractiveness of the material for use in a malicious act).

These aspects would be relevant with each other.

2.10. The application of graded approach in the safety case and safety assessment for the predisposal management of radioactive waste is given in Ref.[15].

RADIATION PROTECTION

2.11. Radiation protection considerations are governed by the principles of justification of a practice, optimization of protection and limitation of individual dose and risk [6, 16]. The management of radioactive waste is considered part of the entire 'practice' giving rise to the waste in the context of the recommendations of the International Commission on Radiological Protection (ICRP) [16] and the International Basic Safety Standards for Radiation Protection and Safety of Radiation Sources (BSS) [6], and as such does not require separate justification.

2.12. Requirements for radiation protection are established at the national level, with due regard to the BSS [6]. These requirements apply to all radioactive waste management activities and facilities. Not all of these safety requirements are addressed in detail in this Safety Guide.

2.13. In particular, the BSS require radiation protection to be optimized for any persons who are exposed as a result of activities in the predisposal management of radioactive waste, with due regard to dose constraints, and the exposures of individuals to be kept within specified dose limits. It is necessary to restrict the normal exposure of individuals, both workers and members of the public, such that neither the total effective dose nor the total equivalent dose to relevant organs and tissues, caused by the possible combination of exposures from authorized practices including waste management dealt with in this Safety Guide exceeds any relevant dose limit specified in Schedule III of the Basic Safety Standards [6]. National regulations will prescribe dose limits for the exposure of workers and members of the public under normal conditions. Internationally accepted values for these limits are contained in Schedule III of the BSS [6]. In addition to the provision for protection against the exposures that will arise from normal operations referred to in the preceding paragraphs, provision is made for protection against potential exposure. Requirements for protection against potential exposure are also established in the BSS [6].

2.14. In relation to any source within a practice, it is necessary to optimize protection and safety so that the magnitude of individual doses, the number of persons exposed and the likelihood of exposure all be kept as low as reasonably achievable, 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 [6]. For occupational exposure and public exposure, registrants and licensees ensure, as appropriate, that relevant constraints are used in the optimization of protection and safety for any particular source within a practice. Specifically, the benefits of choosing particular waste management options (including treatment, minimization, minimization in terms of type, activity and volume, reuse, recycling, pretreatment, treatment and conditioning) should be optimized bearing in mind any additional exposure to workers over and above conventional operation exposures [3, 6].

2.15. The regulatory body should specify, or approve proposals for, the value of dose constraints for the public exposure that apply for discharge control for the particular practice. The choice of a value for a dose constraint should reflect the need to ensure that a representative person dose, both now and in the future, is unlikely to exceed the dose limit, with account taken of contributions of dose expected to be delivered by all other sources to which the representative person could be also exposed. IAEA Safety Guide No. WS-G-2.3 [19] provides recommendations and guidance on setting such limitations and on control of radioactive discharges to the environment.

2.16. The process of optimization of protection and safety measures may range from intuitive qualitative analyses to quantitative analyses using decision aiding techniques, but should be sufficient [6] to take all relevant factors into account in a coherent way so as to :

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

(b) establish, on the basis of the results of the optimization, criteria for the restriction of the magnitudes of exposures and their probabilities by means of measures to prevent accidents and/or to mitigate their consequences.

2.17. The optimization of protection and safety measures for any particular source or facility considered in this Guide should be approached from a systematic point of view. This would balance safety considerations over the whole practice, not simply within an individual activity and must cover the overall operation including waste management. It should be demonstrated that individual doses would remain below established constraints. Dose constraints should have regulatory approval.

2.18. In establishing constraints, the regulatory body should ensure that:

(a) radiation protection of any persons who are exposed as a result of activities in predisposal management of radioactive waste need to be optimized, with due regard to dose constrains, and with the exposure of individuals kept within specified dose limits [6];

(b) such dose constrains will be established so as to ensure, that the cumulative effects of releases from all such activities does not exceed the relevant effective dose limit to any representative person This should also take into account people distant from the source and future generations.

2.19. Management and technical requirements to prevent the occurrence of incidents or accidents and provisions for mitigating their consequences if they do occur are presented in [6, 20].

2.20. When choosing options for the predisposal management of radioactive waste, consideration is given to both the short term and the long term radiological impacts for workers and members of the public; for example, by balancing present day exposures resulting from the dispersal of radionuclides in the environment and potential exposure that could arise in the future from the disposal of radioactive waste [2, 17].

2.21. Doses and risks associated with the transport of radioactive waste are managed in the same way as those associated with the transport of any radioactive material. Safety in the transport of radioactive waste is ensured by complying with the IAEA Regulations for the Safe Transport of Radioactive Material [10].

Radiation protection programme

2.22. A radiation protection programme should be in place that adequately ensures radiation safety and control of the access to areas where radioactive waste is managed [6].

2.23. All the necessary provisions should be in place to keep the exposures below established limits and as low as reasonable achievable, economic and social factors taken into account [6] and to the extent the complexity of the operational activity warrants following the recommendations of appropriate Safety Guides in respect of operational radiation protection [6, 21-23].

2.24. Appropriate radiation monitoring of the areas where waste is managed should be carried out and radiation dosimetry should be provided to the workers who could be occupationally exposed to radiation whilst managing radioactive waste. Material to be removed from controlled areas should be adequately monitored and recorded [6].

ENVIRONMENTAL CONCERNS

2.25. The principal approaches to the predisposal management of radioactive waste are commonly termed ‘delay and decay’, ‘concentrate and contain’ and ‘dilute and disperse’. ‘Delay and decay’ involves holding the waste in storage until the desired reduction in activity has occurred through radioactive decay of the radionuclides contained in the waste. ‘Concentrate and contain’ means reduction of volume and confinement of the radionuclide content by means of a treatment and conditioning process to prevent or substantially reduce dispersion in the environment. ‘Dilute and disperse’ means discharging approved amounts of readily soluble or readily dispersible radioactive materials to the environment in such a way that environmental conditions and processes ensure that the concentrations and sequestering of the radionuclides are reduced to such levels in the environment that the radiological impacts of the released material are acceptable.

2.26. The approaches ‘delay and decay’ and ‘concentrate and contain’ often involve the holding of waste in a storage facility or the emplacement of waste in a disposal facility. Radioactive waste is therefore processed, as necessary, in such a way that it can be safely placed and held in a storage facility or a disposal facility.

2.27. The preferred approach to protection of the environment is to “concentrate and contain” the radionuclides rather than to dilute and disperse into the environment [3]. However, as part of optimized radioactive waste management, the discharge of effluents containing small amounts of radioactive material to the environment, carried out within authorized limits established by the regulatory body may be the most reasonable option. The regulatory body should set the limitations for discharges following the guidance provided in reference [19].

2.28. Requirements for environmental protection that are associated with predisposal management of radioactive waste are established by the relevant national regulatory bodies, with all potential environmental impacts that could reasonably be expected being taken into consideration [2, 6].

Environmental monitoring

2.29. Environmental monitoring should be a condition for authorization [6] for any large waste management facility, but smaller, less complex facilities may not need to perform environmental monitoring. The need for monitoring should be closely linked to the possibility of significant radiation doses to the general public being received [24]. However, a limited amount of monitoring may sometimes be adequate for public assurance purposes. The scope and extension of a monitoring programme, when it will be needed, will be established during the authorization process.

2.30. Environmental monitoring programmes, if mandated, should be established in accordance with the potential risks posed by the waste management facility and the environmental characteristics of the surrounding area. The programme should involve the collection of environmental samples (for example from groundwater, air, dust) and measurement of radiation and contamination levels. When environmental monitoring is indicated, pre-operational monitoring should be carried out to establish the local background level of radiation and concentration of radionuclides in environmental materials, which can vary from location to location [24].

Control of airborne and liquid discharges to the environment

2.31. Safe radioactive waste management includes keeping the release from the various waste management processes as low as reasonably achievable. As part of the management of radioactive waste, effluents may be released into the environment within authorized limits as a legitimate practice.

2.32. References [6, 19] provide requirements and guidance to the regulatory body on setting such limitations. The limitation on discharges should be such as to ensure that radiation doses to members of the public are maintained as low as reasonably achievable economic and social factors being taken into account and that individual dose are within dose constraints established by the regulatory body for that practice. It is recommended that the limitations imposed should ensure that the annual dose to the representative person is no greater than 300 μSv per year from any single facility [19]. The assessment of compliance with the constraint should consider the possibility of having several users of radioactive material or waste management facilities operating in the same area, By means of radiological assessment it should be demonstrated that the proposed discharges result in doses to the public below these levels.

2.33. While limitations could be set for each individual situation, the regulatory requirements could in addition be set on a generic basis using conservative generic assessment models. Such assessments are likely to result in overestimates of radiological impact in individual situations but may be more readily interpreted and followed by users or operators and more easily enforced. Thus in regulating organizations managing small amounts of radioactive waste the regulatory body could conduct the assessment and set generic discharge limitations which become regulatory requirements. Alternatively, the regulatory system can provide for users or operators assistance when they are conducting their own assessments to show that resulting doses would be acceptable in individual situations. However, this needs a much greater level of technical support by the regulator and may not be warranted in many situations.

2.34. The user or operator should demonstrate compliance with the regulatory requirements for discharge limitation by means of monitoring of releases and by monitoring in the environment [6, 19, 24]. The procedures and measurement techniques for such monitoring should be approved by the regulatory body. Records of the results of such monitoring should be kept. Other means of demonstrating compliance, such as estimation of discharges by calculation may be sufficient in some cases, if approved by the regulatory body.

Removal of regulatory control from materials

2.35. The Basic Safety Standards [6] provide that “The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from further regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of such criteria. By means of this approval the regulatory body shall ensure that sources that have been cleared do not again become subject to the requirements for notification, registration or licensing unless it so specifies.” Such clearance levels will take into account the criteria specified in Schedule I “Material may be cleared without further consideration provided that in all reasonably foreseeable situations the effective dose expected to be incurred by any member of the public due to the cleared material is of the order of 10 □Sv or less in a year. To take into account low probability scenarios, a different criterion can be used, namely that the effective dose expected to be incurred by any member of the public for such low probability scenarios does not exceed 1 mSv in a year.”…

2.36. The waste generator or operator should have a formal mechanism in place to demonstrate compliance with regulatory requirements in respect of removing materials from regulatory control. Additionally, there should be compliance with other requirements on release of any other hazardous (e.g. infectious, biological) aspects of the waste. Any radiation markings on materials from which regulatory control has been removed or empty, clean containers should be removed or covered.

2.37. Information on materials from which regulatory control has been removed should be retained and provided to the regulatory body if required.

Removal of regulatory control from buildings and sites

2.38. When buildings and sites are decommissioned and prior of removal of the 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 levels as required by the regulatory body. Further requirements and guidance are provided in Ref. [13, 14, 37].

3. RESPONSIBILITIES ASSOCIATED WITH THE PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

GENERAL

3.1. Management of all radioactive waste should take place within an appropriate national legal framework that clearly assigns responsibilities and that provides for effective regulatory control of activities generating waste and within any facility where such waste is managed. Internationally endorsed requirements on the allocation of such responsibilities, in particular those of the regulatory body, are established in IAEA Safety Standards [4, 6]. However, selected responsibilities of the various parties involved that are specific to the predisposal management of radioactive waste are outlined in the following. Such a framework should also facilitate compliance with other national and international laws and regulations. Although laws are normally of general application, national legal systems may have facility or site specific regulations on management of waste generated from particular activities.

3.2. While safety is the prime responsibility of the operator, to whom the majority of the requirements apply, ensuring safety and developing a broader confidence in safety also requires the establishment of an effective regulatory process within a clearly defined legal framework [4]. The legal framework [4] should ensure that there is a clear allocation of responsibilities for safety during the entire waste management process, including the transfer of such waste or radioactive material and the decommissioning of facilities where the radioactive material may have been used. This continuity of responsibility for safety should be ensured through specification of ownership and clarity of custodianship, enforced where necessary though authorizations and control by the regulatory body.

3.3. 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 stages of waste management and organizations involved.

3.4. It is possible that the predisposal management of radioactive waste will involve the transfer of radioactive waste from one operator to another, or that radioactive waste may even be processed in another State. In such situations, continuity of responsibility for safety is necessary throughout the predisposal process. In the event of the transfer of radioactive waste beyond national boundaries, article 27.1 of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management applies to Contracting Parties to the Joint Convention [25], and compliance with this article is considered good practice for all States. This article concerns the need for the prior notification and consent of the State of destination; the need for adequate technical and administrative capacity in the State of destination and the need to subject transboundary movement through transit States to the relevant international obligations.

3.5. The aim of predisposal radioactive waste management should be to minimize waste generation and to produce a waste form that conforms to the requirements for subsequent handling, processing, transport and storage, or meets the acceptance requirements for disposal. The management option selected may also result in a 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 [3, 6, 19], or removed as discrete entities from regulatory control.

NATIONAL POLICY AND STRATEGY ON PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

Requirement 1 (GSR Part 5, Ref. [4]): Legal and regulatory framework

The government shall provide for an appropriate national legal and regulatory framework within which radioactive waste management activities can be planned and safely carried out. This shall include the clear and unequivocal allocation of responsibilities, the securing of financial and other resources, and the provision of independent regulatory functions. Protection shall also be provided beyond national borders as appropriate and necessary for neighbouring States that may be affected.

Requirement 2: National policy and strategy on radioactive waste management

To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles [2] and with international instruments, conventions and codes that have been ratified by the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste [3].

3.6. The government is responsible for establishing a national policy and corresponding strategies for the management of radioactive waste. The management of radioactive waste should be undertaken within an appropriate national legal and regulatory framework that provides for a clear allocation of responsibilities, and that ensures the effective regulatory control of the facilities and activities concerned [2, 4]. The policy and strategy, as well as the legal framework, should cover all types and volumes of radioactive waste generated in the State, all waste processing and storage facilities located in the State, and waste imported or exported from it, with due account taken of the interdependences between the various stages of radioactive waste management, the time periods involved and the options available.

3.7. The legal framework should also establish measures to ensure compliance with other relevant international legal instruments.

3.8. Where nuclear, environmental, industrial safety and occupational health aspects are separately regulated the regulatory framework should recognize that the overall safety is affected by the interdependences between radiological, industrial, chemical and toxic hazards and ensure that the regulatory framework identifies this and delivers effective control.

3.9. The legal framework should ensure that the construction, adjacent to a facility site, of installations that could prejudice the safety of the facility is required to be monitored and controlled by means of planning requirements or other legal instruments.

3.10. The management of radioactive waste may entail the transfer of radioactive waste from one operating organization to another organization and also from one national or governmental entity to another. Such transfers create interdependences between organizations as well as physical interdependences in the various steps in the management of radioactive waste. The legal framework should include provisions to ensure a clear allocation of responsibility for safety throughout the entire process, in particular with respect to interface with the storage of radioactive waste and its transfer between operating organizations.

3.11. The extent to which on-site waste management is undertaken by an user or operator depends on the options available in terms of the national waste management strategy, the infrastructure of the operator and the technical competence available in relation to the management of the generated waste. On-site waste management can include a full range of operations, such as waste minimization; pretreatment (including segregation, characterization, chemical adjustment); treatment; conditioning; and storage. However, as a minimum, waste minimization, segregation, basic characterization and associated storage should be undertaken on-site.

3.12. In many of the situations covered by this Safety Guide a strategy involving a combination of on-site and collective waste management is appropriate. Thus waste containing short lived radionuclides might be dealt with locally at the site where it is generated and waste with long-lived radionuclides, as it could be the case with the majority of the disused sealed radioactive sources, at a national and/or regional facility.

3.13. The government is responsible for establishing a regulatory body independent from the owners of the radioactive waste or the operating organizations managing the radioactive waste, with adequate authority, power, staffing and financial resources to discharge its assigned responsibilities (GSR Parts 1 and 5) [2, 4].

3.14. Responsibility for safety should be ensured by means of a system of authorization by the regulatory body. For transboundary transfers between States, authorizations from the respective national regulatory bodies are required (GSR Parts 1 and 5) [2, 4].

3.15. Interdependences exist between the various steps in the management of radioactive waste. The national and regulatory framework should incorporate clear definitions of the content and responsibilities for the management of the interdependences.

3.16. A mechanism for providing adequate financial resources should be established to cover any future costs, in particular, the costs associated with the storage of radioactive waste, decommissioning of both the predisposal waste management facilities and the storage facilities and also the costs of long term management of radioactive waste, if applicable. The financial mechanism should be established before licensing and eventual operation, and should be updated as necessary. Consideration should also be given to provision of the necessary financial resources in the event of a premature shutdown of the radioactive waste management facility or an early dispatch of the waste to a disposal facility.

3.17. The government should consult interested parties (i.e. those who are involved in or are affected by radioactive waste management activities) on matters relating to the development of policies and strategies that affect the management of radioactive waste.

3.18. In order to facilitate the establishment of a national policy and strategy, the Government should establish a national inventory of the radioactive waste (actual and expected, such as waste generated during decommissioning and dismantling of facilities) and update it at regular time intervals. This inventory should take into account the guidance in GSG-1 [9].

3.19. Facilities for predisposal management of radioactive waste should have sufficient capacity to process all waste generated and the storage capacity should be sufficient to account for uncertainties in the availability of facilities for treatment, conditioning and disposal.

3.20. The national policy and strategy should address the various waste classes as identified in GSG-1 [9] and their long-term management, from a technical point of view as well as from a resources point of view. It should take due account of social and economic developments.

RESPONSIBILITIES OF THE REGULATORY BODY

Requirement 3: Responsibilities of the regulatory body

The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities and shall set out procedures for meeting the requirements for the various stages of the licensing process. The regulatory body shall review and assess the

safety case[4] and the environmental impact assessment for radioactive waste management facilities and activities, as prepared by the operator both prior to authorization and periodically during operation. The regulatory body shall provide for the issuing, amending, suspension or revoking of licences, subject to any necessary conditions. The regulatory body shall carry out activities to verify that the operator meets these conditions. Enforcement actions shall be taken as necessary by the regulatory body in the event of deviations from, or non-compliance with, requirements and conditions [3].

3.21. General requirements for the protection of human health and the environment are usually stated in national policy and set out in legislation. The regulatory body has to establish regulatory requirements for radiation protection and safety of the radiation sources as well as specific to the predisposal management of radioactive waste, on the basis of national policy and legislation and with due regard to the objectives and principles set out in Section 2 of this Safety Guide [3, 6].

3.22. To facilitate compliance with regulatory requirements [3], the regulatory body:

(a) Provides necessary guidance on the interpretation of national standards and regulatory requirements that take into consideration the complexity of the operations and the magnitude of the hazards associated with the facility and operations (graded approach);

(b) Encourages dialogue between and participates in dialogues with the operator and other interested parties, and to provide advice on development, interpretation and application of legislation and regulations;

(c) Ensures that responsibilities are assigned to appropriate parties who generate or manage radioactive waste for ensuring preparation and keeping of relevant documents and records covering all the waste management steps, that the record keeping is properly implemented and that records are maintained for an appropriate period of time;

(d) Establishes an appropriate definition and/or classification of radioactive waste [26];

(e) Establishes criteria for the clearance of material from regulatory control, in accordance with the national policy [6];

(f) Establishes and clarifies to the operator the processes used to evaluate safety and to review applications;

---

[4] The safety case is a collection of arguments and evidence in support of the safety of a facility or activity. The safety case will normally include the findings of a safety assessment, and will typically include information (including supporting evidence and reasoning) on the robustness and reliability of the safety assessment and the assumptions made therein [1].

(g) Provides licence application requirements to applicants for licences;

(h) Ensures that no activities generating radioactive waste commence without provision for proper management of the radioactive waste and that adequate and suitable storage capacity is available;

(i) Documents the procedures that apply to the mechanisms for compliance verification and enforcement;

(j) Establishes a mechanism by means of which information on incidents significant to safety is disseminated to interested parties;

(k) Enters into agreement, where appropriate, with other governmental bodies responsible for regulation in related fields to delineate areas of responsibility or of cooperation;

(l) Ensures 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;

(m) Establishes safety standards for the decommissioning of facilities including conditions on the end points of decommissioning;

(n) Establishes standards for the removal of materials from regulated facilities or activities and to provide guidance and appropriate regulatory agreement for the authorized discharge of liquids and gases containing radionuclides;

(o) Defines the required time period for which the records by the operator will be retained;

(p) Ensures that its own staff and that of the user or operators have the necessary expertise and competence to perform their functions adequately and where necessary to ensure that adequate training is provided; and

(q) Ensures that due consideration is given to non-radiological hazards throughout the whole predisposal management of radioactive waste.

3.23. The regulatory body will require the user or operator to submit safety documentation in support of an application for a license or other type of authorization involving the management of radioactive waste. The safety case will include a safety assessment report commensurate with the complexity of the facility.

3.24. The regulatory body carries out activities that are necessary to verify that requirements for safety and environmental protection are being met by the operator. These activities are supported by an effective management system, including the establishment and maintenance of a strong safety culture [4, 27].

3.25. To fulfil its regulatory functions, where appropriate, the regulatory body should undertake research, acquire independent assessment capabilities and participate in activities for international cooperation.

RESPONSIBILITIES OF THE OPERATORS (INCLUDING THE WASTE PRODUCER)

Requirement 4: Responsibilities of the operator

Operators shall be responsible for the safety of predisposal radioactive waste management facilities or activities[5]. The operator shall carry out safety assessments and shall develop a safety case, and shall ensure that the necessary activities for siting, design, construction, commissioning, operation, shutdown and decommissioning are carried out in compliance with legal and regulatory requirements [3].

3.26. Operators of facilities handling, using or processing radioactive materials have the primary responsibility for the safe management of any associated radioactive waste [3]. Ideally this should include disposal but where disposal facilities are not available; it should involve safe long term storage. Adherence to the following guidance, details of which may be given by the regulatory body, should enable them to meet the requirements placed on them by Refs [3, 6].

3.27. Before commencing construction or significant modification of any waste management facility or starting any activity that may generate radioactive waste, operators should submit an application to the regulatory body including the information specified in para. 3.23. The application should identify the waste management steps to be followed, including arrangements for storage and disposal, should detail proposed design and operational practices, and should include an explanation of how safety standards would be met.

3.28. Before commencement of operations involving radioactive materials, when required, the operator should carry out commissioning tests approved by the regulatory body, in order to demonstrate compliance with the design and safety standards.

3.29. At the outset of planning for operations, operators should prepare outline plans for eventual decommissioning activities [13, 14].

---

[5] The Basic Safety Standards (BSS) [6] establish general and specific requirements for the allocation of responsibilities for the protection of people against exposure to ionizing radiation and for the safety of radiation sources.

3.30. Depending on the complexity of the operations and the magnitude of the hazards associated with the facility or the activities concerned, the operator has to ensure an adequate level of protection and safety by various means [3]. This should include:

(a) Ensure that the necessary activities for siting, design, construction, commissioning, operation, shutdown and decommissioning are carried out in compliance with legal and regulatory requirements;

(b) Demonstration of safety by means of the safety case and safety assessment, and for an existing facility or activity by means of periodic safety reviews (it should cover all phases of the projected operation, including decommissioning);

(c) Demonstration of environmental protection by means of an assessment, when required, of environmental impacts;

(d) Establishment of a radioactive waste management strategy that includes all waste under the control of the operator, including waste that has arisen from past practices, taking into account interdependencies among all steps in waste management, the available options and the national radioactive waste management policy and strategy as far as applicable;

(e) Derivation of operational limits and conditions as well as administrative controls, including waste acceptance criteria, to assist with ensuring that the predisposal radioactive waste management facility is operated in accordance with the national regulations and the facility-specific safety case;

(f) Ensuring that the generation of radioactive waste is kept to the minimum practicable;

(g) Ensuring that radioactive waste is managed by providing appropriate collection, segregation, characterization, classification, treatment, conditioning, storage and disposal arrangements including timely transfer between waste management steps;

(h) Ensuring that equipment and facilities are available to carry out the radioactive waste management activities safely;

(i) Preparation and implementation of appropriate operating procedures, including monitoring;

(j) Application of good engineering practice and to maintain an awareness of waste management practice and ensure feedback of relevant operating experience;

(k) Ensuring adequate human resources and that the staff is trained, qualified and competent, and, where applicable, licensed by the regulatory body throughout the life cycle of the facility;

(l) Ensuring that there are no unavoidable delays in processing waste and transferring to the next step as soon as practicable, use relevant international experience to ensure operations are as safe as practicable;

(m) Establishment and implementation of a management system [27] that ensures safety, security of all authorized activities and regulatory compliance. This system includes clear delineation of responsibilities, operating procedures, and specifications for record retention and make provision for routine and non-routine reports that are required by the regulatory authority;

(n) Maintenance of records and reports as required by the regulatory body, including those records and reports necessary to guarantee the accountability for and traceability of radioactive waste throughout the different processes of radioactive waste management;

(o) Ensuring the monitoring, recording and reporting to the regulatory body of clearance of materials and discharges with sufficient detail and accuracy to demonstrate compliance with any regulatory requirements, limits and conditions established in the authorization and to report any clearance of materials, discharges or releases exceeding the authorized amounts promptly to the regulatory body;

(p) Providing a record an inventory of radioactive waste generated, held and stored, discharges made and of radioactive material removed from regulated facilities and activities, or transferred to the responsibility of another operator to the regulatory body at such intervals, in such a form and containing such details as the regulatory body may require.

(q) Establishment and maintenance of a mechanism to provide and ensure adequate financial resources to discharge its responsibilities. All phases of the activity and/or facility, including end of life and decommissioning will be covered by the financial assurance;

(r) Assess the integrity of the waste control measures and facilities to ensure that they are fault tolerant;

(s) Development of an emergency preparedness and response plan;

(t) Consideration of non-radiological hazards and conventional health and safety issues; and

(u) Provide such other information on radioactive waste management activities and facilities as required by the regulatory body.

3.31. The operator may use cost-benefit arguments to justify its proposed program, as long as safety limits are respected.

3.32. The operator should handle, process or store, waste in an approved manner using its own facilities or may transfer the waste to the operator of an authorized waste management facility. The operator should ensure that radioactive waste is transferred only in accordance with waste acceptance criteria established by the radioactive waste management facility and that waste consignments are accompanied by the necessary waste inventory information.

3.33. The waste should be transported in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material [10].

3.34. The operator also has full responsibility to ensure that the waste packages comply with acceptance requirements for any long term storage or disposal or with requirements approved or set by the regulatory body.

3.35. Sufficient financial and human resources should be made available by users and operators to ensure that radioactive waste management strategies (programmes) can be carried out safely and in accordance with conditions of authorization.

3.36. Staff with responsibilities for the management of radioactive waste should have the appropriate level of qualifications and experience to discharge their responsibilities competently. They should have the appropriate scientific and/or technical knowledge and an appropriate level of experience.

3.37. Operators should be responsible for the safety of all management activities even if the work is contracted to a third party or until the waste becomes the responsibility of another authorized operator. Where appropriate, the operator may delegate work associated with the aforementioned responsibilities to other organizations, but the operator is required to retain overall responsibility and control.

3.38. The operator is responsible for implementing measures to ensure an appropriate level of security.

3.39. According to [3] the operator is responsible for applying management systems to all steps and elements of the predisposal management of radioactive waste. The operator is required to establish a demonstrated commitment to safety on the part of senior management and to promote a strong safety culture [27, 28, 34].

3.40. According to [3] the operator is responsible for establishing and implementing the overall strategy (waste management programme) for the management of the waste that it generates, and for providing the required financial securities, taking into account interdependences among all steps in waste management, the available options and the national radioactive waste management policy and strategy [3].

3.41. According to [3] the operator is responsible to provide information about changes of ownership of waste or about changes in the relationship between owner and licensee to the regulatory body [3].

3.42. Each operator should appoint an appropriately qualified person with overall responsibility for day to day control over management of radioactive waste. The person may also be the radiation protection officer, depending on the size and complexity of the organization. The appointed person should be given the specific responsibility of advising the management and implementation of all matters relating to the safe management of radioactive waste. Appropriate authority and resources should be provided to him/her in order to ensure that the operator's obligations as specified in this subchapter are carried out. This person may have among others the following responsibilities:

(a) make and maintain contact with all relevant persons involved with radioactive waste to provide an authoritative point of advice and guidance;

(b) liaise as needed with the Radiation Protection Officer and with other radioactive waste management organizations;

(c) establish and maintain a detailed record-keeping system for all stages of radioactive waste management, including the inventory of radioactive waste;

(d) ensure proper radioactive waste conditioning when appropriate;

(e) ensure that on-site transfer of radioactive waste is carried out in accordance with written safety procedures;

(f) ensure that waste packages for off-site transportation are prepared to be in compliance with transport regulations;

(g) elaborate, review and update the safety case and safety assessment;

(h) obtain approval from the regulatory body for any new activity or facility dealing with radioactive waste management and transport of radioactive waste;

(i) ensure appropriate shielding, labelling, and integrity of waste packages;

(j) ensure that any discharge of effluents is made below the limits authorized by the regulatory body and kept as low as reasonably achievable;

(k) ensure that solid waste disposed of in a municipal landfill is in accordance with clearance levels established by the regulatory body;

(l) report on incidents, accidents and inappropriate waste management practices to the licensees' management; and,

(m) maintain an up-to-date knowledge and records of the characteristics of discharge and disposal options.

Emergency preparedness

3.43. The operator should establish and maintain emergency preparedness and response plans commensurate with the hazards associated with the radioactive waste facilities and activities, and should report incidents significant to safety in a timely manner to the regulatory body and other interested parties, as appropriate [20].

3.44. The emergency plan should include, as a minimum, training of staff to be competent to recognize and react to an accident or emergency, assignment of responsibilities of various parties involved and appropriate arrangements and equipment to ensure the protection of emergency workers. Requirements and further guidance in relation to emergency preparedness and response are given in Ref. [20, 21].

INTEGRATED APPROACH TO SAFETY

Requirement 5: Requirements in respect of security measures

Measures shall be implemented to ensure an integrated approach to safety and security in the predisposal management of radioactive waste [3].

Requirement 21 (GSR Part 5, Ref. [4]): System of accounting for and control of nuclear material

For facilities subject to agreements on nuclear material accounting, in the design and operation of predisposal radioactive waste management facilities the system of accounting for and control of nuclear material shall be implemented in such a way as not to compromise the safety of the facility.

3.45. Physical security arrangements at facilities where radioactive waste is generated or managed should be in place to ensure that radioactive waste is not accidentally or deliberately removed from their proper location without authorization. Particular attention should be given to materials or equipment of intrinsic value or that could pose a serious threat to human health or the environment if control were lost

3.46. The operator should assess and manage the interfaces between nuclear security, safety and nuclear material accountancy and control activities in a manner to ensure that they do not adversely affect each other and that, to the degree possible, they are mutually supportive.

3.47. Where security measures are necessary to prevent the unauthorized access of individuals and the unauthorized removal of radioactive material, both safety and security are to be approached in an integrated manner [2, 3].

3.48. When material is required to be accessed for waste management or safeguard purposes this should take account of requirements for radiation protection, and waste management as well as nuclear security considerations.

3.49. The level of security is required to be commensurate with the level of radiological hazard and the nature of the waste [29].

3.50. For facilities subject to agreements on nuclear material accounting, in the design and operation of predisposal radioactive waste management facilities the system of accounting for and control of nuclear material will be implemented in such a way so as not to compromise the safety of the facility and vice versa [30-32].

INTERDEPENDENCES

Requirement 6: Interdependences

Interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option, shall be appropriately taken into account [3].

3.51. Interdependences exist among all steps in the management of radioactive waste, from the generation of the waste up to its disposal or, as far as practicable, removal of radioactive material within authorized practices from any further regulatory control and the control of discharge. In selecting strategies and activities for the predisposal management of radioactive waste, planning should be carried out for all the various steps so that a balanced approach to safety is taken in the overall management programme and conflicts between the safety requirements and operational requirements are avoided. There are various alternatives for each step in the management of radioactive waste. For example, treatment and conditioning options are influenced by the established or anticipated acceptance requirements for disposal.

3.52. Thus it is important to highlight that the interdependences should be taken into consideration such to ensure that an integrated approach to safety is adopted; and that safety (within a waste management framework that also takes into consideration as far as reasonable achievable waste minimization via adoption of the waste management hierarchy) is optimized.

3.53. The following aspects in particular should be considered:

(a) The identification of interfaces and the definition of the responsibilities of the various organizations involved at these interfaces;

(b) The establishment of acceptance criteria, where necessary, and the confirmation of conformance with the acceptance criteria by means of verification tests or the examination of records.

3.54. Site and facility waste management programmes should identify all relevant interdependences and include arrangements to ensure that they are appropriately considered from the point of generation to the point of disposal. For example, the waste acceptance requirements for disposal should be known and appropriately considered when the waste is generated, recognizing that at the point of generation the controls and information associated with the waste will be aligned with the next stage of predisposal management of radioactive waste and that of the disposal facility. Thus the waste acceptance criteria for each step of predisposal management of radioactive waste should be aligned with the waste acceptance criteria of the next step of predisposal management of radioactive waste ultimately up to the waste acceptance requirements of the disposal facility. If a disposal facility is not yet available, reasonable assumptions should be made on the acceptance requirement

4. STEPS IN THE PREDISPOSAL MANAGEMENT OF RADIOACTIVE WASTE

GENERAL

4.1. Various factors, including the nature and the amount of radioactive waste, occupational and public exposures, environmental effects, human health, safety, and social and economic factors, are to be considered when deciding between options in the predisposal management of radioactive waste. However, the preferred option, as far as is reasonably practicable, is to concentrate and contain the waste and to isolate it from the biosphere.

4.2. In the predisposal management of radioactive waste, decisions often have to be made at a time when no disposal facility is available and the waste acceptance criteria for disposal are unknown. A similar situation would arise if radioactive waste were to be stored over long periods of time for reasons of safety or for other reasons. In both cases consideration has to be given to whether, for the purposes of safety, the radioactive waste will be stored in a raw, a treated or a conditioned form. For example, in the case of disused sealed radioactive sources, preference is given to the conditioning option with the possibility of later retrieving the source for disposal. The anticipated needs for any future steps in radioactive waste management should be taken into account as far as are possible in making decisions on the processing of the waste.

4.3. Predisposal management of radioactive waste includes a number of processing activities which cover pretreatment, treatment, and conditioning. It also includes various storage and handling operations and transport to a centralized waste management facility and/or to a disposal facility. The management of lesser quantities of waste can be performed at the site of its generation (such as hospital, laboratory, research centre) and/or at a centralized waste management facility.

RADIOACTIVE WASTE MANAGEMENT AND CONTROL INCLUDING MINIMIZATION

Requirement 8: Radioactive waste generation and control

All radioactive waste shall be identified and controlled. Radioactive waste arisings shall be kept to the minimum practicable [3].

4.4. The regulatory body should require the operator to submit, as part of the authorization process, specific comprehensive information on the provision adopted to ensure the waste minimization as far as reasonable achievable. Measures to control the generation of radioactive waste, in terms of both volume and radioactivity content, are considered before the construction of and throughout the lifetime of a facility, beginning with the design phase, through the selection of materials for the construction of the facility, and by the control of materials and the selection of the processes, equipment and procedures used throughout the operation and decommissioning of the facility. The control measures should be generally applied in the following order: reduce waste generation, reuse items as originally intended, recycle materials and, finally, consider disposal as radioactive waste.

4.5. Careful planning is applied to the siting, design, construction, commissioning, operation, shutdown and decommissioning of facilities in which waste is generated, to keep the volume and the radioactive content of the waste arisings to the minimum practicable [2, 3].

4.6. As a first priority the operator should adopt any available provision to avoid the generation of radioactive waste, for example through appropriate design and operation of the respective facilities and using whenever possible radionuclides of relatively short half-life that will decay to insignificant levels within a short time scale. As a second priority, the operator should consider recycle and reuse of radioactive material, equipment, etc. to reduce the amount of radioactive waste to be managed and disposed. Waste minimization is an important step in waste management and controlling potential risk. The implications of minimizing the generation of waste should be assessed as part of the safety assessment and safety case.

4.7. For reasons of safety, unnecessary materials should not be taken into radiologically controlled areas. This reduces the potential generation of radioactive waste, and the spread of radioactive contamination and minimizes waste volumes.

4.8. Another essential aspect of waste minimization is to use the minimum quantity of radioactive material consistent with achieving the objective of the application. Controlling and optimizing the procurement of radioactive materials should be considered.

4.9. Wherever possible, when purchasing sealed radioactive sources, contractual arrangements should allow the return of sources to the manufacturer or pre-determined waste manager following use. This is particularly important for high activity sources from which regulatory control cannot be removed until after many years of decay storage or for sources containing long lived radionuclides.

4.10. The reuse and recycling of materials is applied to keep the generation of radioactive waste to the minimum practicable, provided that protection objectives are met.

4.11. Reuse and/or recycling of radioactive materials should be considered as an alternative to disposal if circumstances permit. The safety of reuse and/or recycling should be assessed before operations are started and, where risks may arise outside the authorized undertaking, the required approvals from the regulatory body should be obtained. Recycling and reuse can involve the following activities:

(a) reuse of sealed radioactive sources by the owner or a new owner with appropriate legal provisions;

(b) recycling of sealed radioactive sources by the manufacturer;

(c) decontamination and/or reuse of material, such as equipment, protective clothing; and

(d) recycling and reuse of materials that fulfil the conditions for removal of control from materials defined by the regulatory body.

4.12. The authorized discharge of effluent and clearance of materials from regulatory control, after some appropriate processing and/or a sufficiently long period of storage, together with reuse and recycling of material can be effective in reducing the amount of radioactive waste that needs further processing or storage. The operator should ensure that these management options, if implemented, are in compliance with the conditions and criteria established in regulations or by the regulatory body. The regulatory body should also ensure that the operator gives due consideration to non-radiological hazards in applying such options.

4.13. The operator, in order to keep the generation of radioactive waste to the minimum and in addition to the above mentioned recommendations, should adopt provisions such as:

(a) Careful control of the collecting, segregating, packaging and handling of radioactive materials;

(b) Adopting good segregation practices, including clearance of materials, at point of waste generation;

(c) Efficient operation of collecting and processing systems for gaseous and liquid radioactive waste;

(d) Taking precautions to avoid the contamination of materials, equipment and building surfaces in order to reduce the need of decontamination;

(e) Restrictions on taking packaging and other unnecessary material into the controlled area;

(f) Planning and performing periodical surface monitoring and maintenance work with due care and with particular emphasis on precautions to avoid the spread of contamination;

(g) Creating and maintaining proper record system that would allow the periodical assessment of the effectiveness of measures adopted to minimize radioactive wastes generation. The system should include the definition of measurable indicators to assess the effectiveness of the applied system.

4.14. The non-radiological hazards of waste should also be minimized. Mixing of radioactive waste with toxic or hazardous materials should be avoided. For example, it would be preferable to use a thermocouple for temperature measurement rather than a mercury glass thermometer to avoid the possible formation of a waste stream containing contaminated mercury.

CHARACTERIZATION AND CLASSIFICATION OF RADIOACTIVE WASTE

Requirement 9: Characterization and classification of radioactive waste

At various steps in the predisposal management of radioactive waste, the radioactive waste shall be characterized and classified in accordance with requirements established or approved by the regulatory body [3].

4.15. Radioactive waste has to be characterized in terms of its physical, mechanical, chemical, radiological and biological properties [3].The characterization serves to provide information relevant to process control and assurance that the waste, the waste form or waste package will meet the acceptance criteria and/or requirements for processing, storage, transport and disposal of the waste. The relevant characteristics of the waste should be recorded to facilitate its further management.

4.16. Characterization can be used for different purposes, such as identifying the potential hazards associated with the particular types of waste, designation of waste to decay, particular processing, storage or disposal option and planning and designing waste management facilities. Reference [35] provides advice on waste characterization. The data from the characterization processes should be recorded and a record should be maintained for an appropriate period of time.

4.17. Classification enables selection of the most appropriate waste management option and is often considerably influenced by radioactive half-life. Waste containing radionuclides with short radioactive half-lives which can be managed by safe storage until decay to insignificant levels should be segregated with priority. In this context due consideration should be given to impurities with long radioactive half-lives, which are not always detectable during the original characterization of short lived waste. The most common classification is that made from the perspective of its future disposal [26].

4.18. Radioactive waste generated from use of radioactive materials can generally be categorized for operational purposes into the following main groups: solid waste, liquid waste and gaseous waste. The waste in the groups may consist of waste with radionuclides which are differentiated by activity (alpha, beta–gamma and neutron emitters), half-life, and by the physical, mechanical chemical and biological properties of the waste matrix.

4.19. To ensure that waste will be handled effectively when being transferred between operators, the regulatory body should ensure the operator evaluates proposed categorization schemes for conformity with relevant waste acceptance criteria established for subsequent steps.

4.20. In order to ensure the proper interdependence among all steps in radioactive waste management, the operator should take into account in the development of the categorization scheme the acceptance criteria and/or requirements established for the subsequent handling, processing, transport, storage and disposal steps, within the waste management overall process.

PROCESSING OF RADIOACTIVE WASTE

Requirement 10: Processing of radioactive waste

Radioactive material for which no further use is foreseen, and with characteristics that make it unsuitable for authorized discharge, authorized use or clearance from regulatory control, shall be processed as radioactive waste. The processing of radioactive waste shall be based on appropriate consideration of the characteristics of the waste and of the demands imposed by the different steps in its management (pretreatment, treatment, conditioning, transport, storage and disposal). Waste packages shall be designed and produced so that the radioactive material is appropriately contained both during normal operation and in accident conditions that could occur in the handling, storage, transport and disposal of waste [3].

4.21. The regulatory body should establish requirements and criteria pertaining to the safety of all processes and operations encompassed in the predisposal management of radioactive waste.

4.22. Processing of radioactive waste can involve a number of operations that change the characteristics of the waste and involve pretreatment, treatment and conditioning steps. Processing may be necessary for safety, technical or financial reasons. From a safety perspective, processing is necessary to eliminate or reduce associated hazards (for example radiological, physical, chemical, and biological). Waste should only be processed after its precise characterization. Processed waste should also be characterized, in order to supply the required data for the subsequent waste management steps.

The methods for processing should be selected on the basis of the waste characteristics and the established national policy and strategy for radioactive waste management.

4.23. The main purpose of processing radioactive waste is to enhance safety by producing a waste form, packaged or unpackaged, that fulfils the acceptance criteria for safe processing, transport, storage and disposal of the waste. Waste has to be rendered into a safe and passive form for storage or disposal as soon as possible [3]. Radioactive waste has to be processed in such a way that the resulting waste form can be safely stored and retrieved from the storage facilities up until its ultimate disposal or clearance (in case of decay storage). Waste packages have to be designed and produced so that the radioactive material is appropriately contained during both normal operation and in accident conditions that could occur in the handling, storage, transport and disposal of waste [3].

4.24. Waste has to be processed in such a way that safety is appropriately ensured during normal operation, that measures are taken to prevent the occurrence of incidents or accidents, and that provisions are made to mitigate the consequences if accidents occur. The processing has to be consistent with the type of waste, the possible need for its storage, the anticipated disposal option, and the limits, conditions and controls established in the safety case and in the assessment of environmental impacts [3].

4.25. Various methods are applied for processing radioactive waste of different types. Consideration has to be given to identifying suitable options and to assessing the appropriateness of their application. Decisions have to be taken within the overall approach to the predisposal management of radioactive waste on the extent to which the waste has to be processed, with account taken of the quantities, activity and physical and/or chemical nature of the radioactive waste to be treated, the technologies available, the storage capacity and the availability of a disposal facility [3].

4.26. Provisions have to be established by the operator for identifying, assessing and dealing with waste, waste forms and/or waste packages that do not meet process specifications and requirements for its and/or their safe handling, transport, storage and/or disposal.

4.27. The generation of secondary radioactive waste should always be taken into account when selecting a processing method. Consideration has to be given to the consequences of dealing with any secondary waste (both radioactive and non-radioactive) that is generated in processing [3]. The implications of secondary waste arising should be taken into account in the safety and environmental impact assessment. This is of particular concern with operations such as decontamination, sawing and cutting, shredding and crushing of solid waste for volume reduction purposes. The processing of radioactive waste can yield effluent that is suitable for authorized discharge or material that is suitable for authorized use or clearance from regulatory control.

4.28. In selecting the method for processing radioactive waste, due consideration should be given to the exposure of workers, both in normal operation and due to potential incidents and accidents posed by each processing method.

4.29. The regulatory body should be aware that other regulatory organizations e.g. those responsible for transport, may be involved in the transfer of radioactive waste to a subsequent management step. Timely liaison with these organizations should be considered in order to avoid unnecessary delays and duplication of process.

Pretreatment

4.30. Pretreatment of radioactive waste is the initial step in its management carried out following generation. Pretreatment activities include collection, segregation, chemical adjustment and decontamination as defined in the waste management strategy. For this initial step waste streams should be segregated at the source of generation and, as a prerequisite, adequate waste identification and classification should be performed according to the classification scheme in place. Operators of centralized waste management facilities receiving radioactive waste should verify the waste characteristics by routine or random measurements or other means in order to confirm the information provided by the users and to facilitate the selection of suitable treatment and conditioning techniques. An updated record of the waste characteristics should be maintained as part of the quality assurance programme.

4.31. Generally, the collection and segregation of different types of radioactive waste should be undertaken on the basis of a defined strategy (programme) for radioactive waste management and the available waste management infrastructure or the acceptance requirements of a radioactive waste management facility. The objective of waste segregation is to minimize the volume, cost, complexity and risks associated with subsequent waste management steps. The operator should adopt provisions to ensure that after segregation each waste stream is kept in separated, appropriated and properly identified and labelled containers. Segregation of radioactive waste should be performed according to a categorization scheme to allow for safe and adequate accomplishment of further predisposal steps. Particular attention should be given to the segregation of higher activity waste particularly during decommissioning. This facilitates recycling within the process or disposal as non-radioactive waste when the quantities of radionuclides present in the waste are sufficiently low to enable it to be removed (cleared) from a regulated facility or activity.

4.32. The containers used during collection and segregation of radioactive waste should be physically and chemically compatible with the waste and provide adequate containment of the material and provide protection to the workers from any chemical, biological, physical or other hazards (such as injury from contaminated sharp objects). Materials used should be mechanically robust and where appropriate, such as for biological radioactive waste, use should be made of double wrapping or a suitable outer container.

4.33. Containers for solid wastes should be lined with a durable plastic bag that can be sealed (tied with plastic adhesive tape, heat-sealed with a radio-frequency welder). Sharps should be collected separately and stored in rigid, puncture-resistant containers (preferably metal) that have been clearly labelled 'sharps'. Damp solid waste and liquid waste should be collected in suitable containers according to the chemical and radiological characteristics, volume of the waste, handling and storage requirements. Normally double packaging is used.

4.34. Disused sealed radioactive sources should be kept in their shielding. When the shielding is contaminated, it should be decontaminated or overpackaged to avoid the further dispersal of contamination.

4.35. The containers should be appropriately identified and labelled, and distributed in relevant working places where the radioactive waste is expected to be generated. Consideration should be given to the safe handling of the waste containers (for example, by providing refuse cans with foot pedals) and their use in the next waste management stages. As soon as radioactive waste accumulation commences, information on the nature of the waste collected should be recorded by the user. Containers should be checked for radioactive contamination and loose contamination should be removed before reuse. The following information should be recorded for each waste container:

(a) identification number;

(b) radionuclides;

(c) activity (measured or estimated) and date of measurement;

(d) origin (e.g. room, laboratory);

(e) actual/potential hazards (e.g. chemical, infectious);

(f) surface dose rate and date of measurement;

(g) quantity (weight or volume); and

(h) responsible person.

4.36. Segregation of radioactive waste should be performed taking into consideration primarily:

(a) activity and radionuclides present;

(b) half-life of radionuclides present: short lived radionuclides (for example half-lives not exceeding 100 days) suitable for decay storage or long lived radionuclides (for example half-lives exceeding 30 years);

(c) physical and chemical form of the waste, such as:

– combustible, non-combustible, compressible, non-compressible, aqueous, organic, homogeneous, non-homogeneous (contain sludge or suspended solids) etc.

– non-radiological hazards (toxic, pathogenic, infectious, genotoxic, biological, pharmaceutical or mixed properties);

(d) further processing, storage or disposal activities.

4.37. Decontamination should be carried out only if it is ensured that the following aspects have been evaluated:

(a) the presence of a removable layer;

(b) the extent and nature of the surface contamination;

(c) volume, activity and characteristics of the estimated radioactive waste arising; and

(d) the potential hazards associated with the decontamination method to be used.

4.38. The operator should gather and record in a systematic manner information related to the safety of the next waste management stage. Appropriate precautions should be taken (for example radiological monitoring, decontamination) before a radioactive waste container is transferred for further management.

Treatment

4.39. Treatment of radioactive waste includes those operations intended to provide for safety technical and financial considerations by changing the characteristics of the radioactive waste. The basic treatment concepts applicable are volume reduction, removal of radionuclides and change of composition.

Solid radioactive waste

4.40. A variety of options exist for the treatment of solid waste (see Appendix III). In general they are not applicable to disused sealed radioactive sources, with the exception of conditioning. Potential options for the treatment of solid waste and major safety considerations are listed below:

(a) Compaction should be carried out only if it is ensured that:

– there is no waste that could damage the waste package;

– hazardous (such as infectious) waste is excluded (or disinfected) to avoid release (such as of micro-organisms);

– pressurized containers are excluded to avoid uncontrolled releases of gas or contamination;

– liquids are excluded to avoid leakage from the package during compaction;

– disused sealed sources are excluded to avoid high risks of contamination and exposure;

– loose, active powders are excluded to avoid risks of contamination; and

– chemically reactive materials are excluded to avoid uncontrolled reactions.

(b) Incineration should be carried out only if it is ensured that:

– there are not disused sealed radioactive sources which are excluded to avoid high risks of contamination;

– pressurized containers are excluded to avoid uncontrolled gas and/or contamination releases;

– volatile toxic materials are excluded, if the incinerator is not designed for them;

– materials with a high moisture content are controlled to ensure complete combustion;

– there will be subsequent management of active ash;

– frozen materials are controlled to ensure complete combustion;

– active dust control is applied, particularly from ash handling; and

– treatment and control of the generated exhaust gases is in place and gaseous effluents are discharged within the authorized limits.

Liquid radioactive waste

4.41. A range of options exists for the treatment of liquid radioactive waste. Selection of the optimum treatment process for liquids depends on safety, technical and financial considerations. The treatment of liquids also depends on the kind of liquid (aqueous or organic), the content of solid particles, pH, content of salts, acids, and the possibility of their removal. The treatment process should be carried out in accordance with criteria derived from the national policy and strategy as well as the safety case and supporting safety assessment, and should be implemented through formally approved operating instructions. Adequate safety monitoring should also be provided.

4.42. Liquid radioactive waste streams should be segregated if they vary greatly in chemical or radionuclide content. For instance, solutions of different chemical properties should be stored separately if immediate discharge is not possible. Uncontrolled chemical reactions which may produce heat, aerosols or precipitates should be prevented. An example is the need to segregate acidic solutions from alkaline solutions since change of pH or redox conditions might lead, for instance, to the release of volatile radionuclides such as iodine.

4.43. Combining of liquid streams should only be carried out if the safety assessment has demonstrated the procedure to be acceptable, and if it is documented according to the approved operating instructions. In general, mixing of dissimilar waste streams (such as aqueous and organic, waste containing short and long lived radionuclides) should be avoided unless there is a specific purpose (such as neutralization). In this way the complexity and potential hazards of the waste streams are minimized.

4.44. Different processes for the treatment of aqueous and organic waste streams may be applied. For small amounts of aqueous radioactive waste direct discharge to the normal sewage system or directly to the receiving water body can be authorized by the regulatory body after its justification in the safety assessment. Further discussion is provided in Ref. [6, 19]. For other aqueous waste, chemical precipitation, evaporation, ion exchange, and ultrafiltration processes are all utilized.

4.45. When making use of the chemical precipitation consideration should be exercised over the generation of secondary waste, the possibility of creating heterogeneous waste streams and the need for subsequent conditioning of the active precipitate. For the evaporation process, the following should be considered: the generation of secondary waste; the integrity of the evaporator (in terms of corrosion resistance); the potential fire risk if volatile organic materials are present; the containment of radioactive spray as well as the subsequent conditioning of active concentrates. When using ion exchange process consideration should be given to the generation of secondary waste needing specialized conditioning; the reactivity of the resins with strong oxidants (such as strong nitric acid); the radiolytic degradation of resins; and the spent resin produced that needs specialized conditioning. The use of ultrafiltration necessitates consideration of the leakage from high pressure systems possibly leading to inadvertent dispersal of liquid waste and the subsequent need for conditioning active solids or sludges.

4.46. For organic waste, incineration (with the exception of low flash point or volatile toxic materials), immobilization and absorption processes may be applied. When incineration is used, consideration should be given, as a minimum, to the possible environmental implications of discharging both gaseous and particulate matter and both the radioactive and non-radioactive components. Similarly, consideration should be given to minimizing the generation of airborne radioactive material inside the facility, in which the waste is generated, particularly in handling ash, as well as subsequent management of contaminated ash. In relation to the immobilization and absorption processes, long term stability of the final waste form should be evaluated.

4.47. Concentrates arising from the treatment of liquid radioactive waste (secondary waste) should be immobilized to produce a stable, solid waste form. Waste forms should be produced to be in accordance with criteria, established at the basis of the safety assessment, which take into account the requirements for transportation, storage and eventual disposal.

Airborne discharges

4.48. For small amounts of gaseous effluents, direct discharge to the atmosphere is generally possible within established licensing conditions. In such cases additional treatment of the gaseous effluents is unlikely to be necessary. This is often the case at medical and small research laboratories where the amounts of radionuclides used are small and are often of short half-life.

4.49. Airborne discharge streams containing particulate radioactive material should where necessary be cleaned by means of filters or by other means prior to release to the atmosphere. Unless only contaminated with short lived radionuclides, the filter or other cleaning medium should be treated as solid radioactive waste. If only short lived radionuclides are deposited on the filter or other cleaning medium it can be allowed to decay without the need for further treatment and then be removed from regulatory control.

Biological radioactive waste

4.50. Radioactive waste of a biological nature should be managed by taking into consideration the associated radiological and non-radiological hazards (biological and/or infectious; physical, chemical flammable and/or explosive hazards). For infectious biological waste from medical applications, pretreatment should be undertaken to eliminate all infectious agents before the waste is stored and/or disposed of. A flow diagram illustrating the management of biological waste is given in Appendix IV.

4.51. Practices for radioactive waste management are not usually appropriate or sufficient to control biological hazards. At the same time biological radioactive waste cannot always be treated using the same methods as non-radiological biological waste. A number of options do exist for the processing of biological radioactive waste involving steam sterilization, chemical disinfection, dry heat treatment and sterilization by irradiation. Thermal processes such as incineration, steam autoclaving, microwave processing and dry heat are used primarily to destroy organics and micro-organisms present in the waste. Chemical processes are used to decontaminate biological waste by disinfection.

Conditioning of radioactive waste

4.52. Conditioning of radioactive waste involves those operations that convert the processed waste into a form which is suitable for handling, transportation, storage and disposal. In selecting a conditioning process, depending on the type of waste and the national policy and strategy, the licensee should consider the following aspects:

(a) Whether safety would be improved from the use of a matrix material;

(b) Compatibility of the radioactive waste with the selected materials and/or a waste container; and processes;

(c) The minimization of the generation of secondary radioactive waste;

(d) The result of the conditioning process should be compatible with next step of management or the endpoint for the waste (e.g. long-term storage versus disposal); and

(e) The use of Waste Acceptance Criteria and/or waste acceptance requirements (for disposal), which are developed by the waste operator and approved by the regulatory body.

4.53. The operations may include immobilization of the waste in a matrix, placing the waste into a container and providing additional packaging. In many instances, pretreatment, treatment and conditioning take place in close conjunction with one another.

4.54. The conditioning of radioactive waste should ensure maximum compatibility between the waste, the matrix, and the container; maximum homogeneity and stability of the waste form; minimum content of free liquid in the waste form; minimum free space in the container; maximum container durability; and low leachability, as well as control over the complexing agents and organic compounds. The operations may include immobilization of the waste in a matrix. The operator should ensure that the waste packages are designed and produced so that radionuclides are confined under both normal conditions and accident conditions that may occur during handling, storage, transport and disposal. The relevant acceptance requirements and criteria should be approved by the regulatory body.

4.55. Consideration should be given in the safety assessment and safety case to the materials to be conditioned and the relevant acceptance requirements and/or criteria for storage and disposal of the waste. The latter should be authorized by the regulatory body. Ref. [37] provides technical guidelines for the development of waste package specifications that comply with acceptance requirements for storage and disposal of radioactive waste.

4.56. In making the assessment, it is useful to view the radioactive waste package as consisting of two principal components, that is, the waste form and the container. The nature of the waste form in the container has a significant effect on the properties of the overall waste package and can influence the performance of the package with respect to the relevant acceptance criteria.

4.57. The operator should ensure that each waste package is provided with a durable label carrying the identification number and relevant information and that a proper record of each waste package is kept as part of the management system. All records should be securely stored, easily accessible and be able to be retrieved over an extended period. Information should include as a minimum for each individual package:

(a) origin of waste;

(b) identification number of the package;

(c) type and design details of the package and unloading documentation;

(d) weight of package;

(e) external size and/or volume of the package;

(f) maximum dose rate at contact and 1 m (transport index) and date of measurement;

(g) results of surface contamination measurement and date of measurement;

(h) radionuclide and activity content;

(i) fissile material content (such as ^{239}Pu–Be sealed sources) if applicable;

(j) physical nature; and

(k) presence of potential pathogenic, chemicals, asbestos, organic matters, and other materials of potential hazards

4.58. .The operator should ensure that each waste conditioned package can be transported in accordance with national regulations and in compliance with the IAEA Transport Regulations [10, 11]."

4.59. Since the waste packages may be stored for a long time prior to disposal, quality control of the conditioning process and produced wastes packages is a key aspect to be considered by the operator.

As part of the management system of the operator, measures for quality assurance and control should be implemented to the packaging of waste to ensure compliance with the waste acceptance requirements for the selected or anticipated disposal option. The quality control should include, but is not limited to:

(a) the definition of quality standards applying to waste packages;

(b) an unambiguous definition of quality indicators for the conditioning processes as well as for the final packages. The quality indicators should demonstrate that the packages meet specified requirements and acceptance criteria;

(c) the development of a testing program to verify the performance of the packages;

(d) appropriate record keeping; and

(e) making available technical support for radiological and non-radiological measurements and procedures.

Discharge or release of radioactive materials to the environment

4.60. Operator should ensure that radioactive materials and sources from authorized practices are not discharged to the environment unless:

(a) Such discharge is within the limits specified in the license and is carried out in a controlled manner according to the regulation in force and the authorization issued by the regulatory body methods; or

(b) The activity discharged is confirmed to be below clearance or other discharge levels established by the regulatory body.

4.61. Before initiating the discharge to the environment, the operator should apply for an authorization demonstrating that he has:

(a) determined the characteristics and activity of the material to be discharged, and the potential points and method of discharge;

(b) determined the potential environment impact from the proposed discharges by use of an appropriate pre-operational study. The study should include:

- all significant exposure pathways by which dischargeable radionuclides can deliver public exposure;
- assessment of doses to the representative person; and

– consideration of the non-radiological hazards;

(c) optimized radiation protection measures.

4.62. The operator should propose discharge levels based on an assessment of the radiological impacts of such discharges using appropriate modelling. Expected doses to the most highly exposed individuals should be estimated. It may be necessary to conduct a survey of life-style of the members of the public to establish the members of the public, who would be highly exposed as a result of the discharges (representative person) [6].

4.63. As part of the discharge control the operator should establish and document technical procedures to carry out discharge operations, as well as define the involvement of individual responsibility.

4.64. Compliance with authorized discharge limitations should be demonstrated through the monitoring of discharges by approved methods of sampling and measurements.

4.65. Consideration should be given to including abnormal environmental discharges in site emergency arrangements.

4.66. Further guidance on radioactive discharges can be found in WS-G-2.3 [19]

4.67. During the operational stage the operator, in addition to above mentioned, should:

(a) keep all radioactive discharges as far below the authorized limits as is reasonably achievable;

(b) not deliberately dilute material, other than the dilution that takes place in normal operations;

(c) monitor and record the discharges of radionuclides with sufficient detail and accuracy to demonstrate compliance with the authorized discharge limits and to permit estimation of the exposure of the representative person;

(d) maintain an appropriate management system for the activities related to effluent or environmental monitoring; and

(e) report discharges to the regulatory body at intervals as may be specified in the license; and, promptly when any discharges will exceed the authorized limits.

4.68. The operator should review operating experience of discharges and, in agreement with the regulatory body, adjust their discharge control measures to ensure optimization of discharges.

Clearance and its control

4.69. In an application for authorization, the operator should declare its intention to clear materials from the regulatory framework during the operational phase.

4.70. In regard to clearance and its control, the operator should adopt provisions to ensure that:

(a) The clearance of radioactive waste complies with clearance levels established by the regulatory body.

(b) A formal mechanism is in place, including rigorous control measures, to demonstrate compliance with regulatory requirements in respect of clearance.

(c) Deliberate dilution of material, other than the dilution that takes place in normal operations will not be carried out.

(d) Any radiation markings will be removed from any material of which regulatory controls no longer apply.

4.71. Information on material which has been removed from regulatory control need to be recorded, retained within a management system and reported to the regulatory body as required.

4.72. Control measures for release of radioactive materials may include:

(a) Determination of the activity concentration of the waste;

(b) Segregation of such waste designated for decay; and

(c) Sampling of each batch of waste prior to removal from control.

4.73. The regulatory body should provide guidance on the content and scope of the information to be submitted by an applicant seeking authorization to release waste with radionuclide concentrations exceeding clearance levels. General requirements and recommendations on this regard are provided in [6, 12].

4.74. Whenever the activity concentrations exceed the clearance levels and the removal from regulatory control appears to be the optimum option for the management of radioactive materials, the operator may consider seeking regulatory approval.

Disused sealed radioactive sources

4.75. Sealed radioactive sources have a wide range of activities depending on their original intended use: from a few megabecquerels calibration sources up to many terabecquerels for medical teletherapy sources. Whilst disused sealed radioactive sources may be a small fraction in terms of the volume of the radioactive waste generated by a particular operator, they may dominate in terms of the activity content of the radioactive waste generated. It is essential to note that, although the radiation output of teletherapy and other large disused sealed radioactive sources may have fallen below useful levels for their initial purposes, the potential for radiation induced injury from such sources remains substantial. It should be noted that Cs-137 teletherapy sources may contain caesium compounds of a dispersible form and can represent a very significant hazard should their primary containment be breached.

4.76. Operator should review their radioactive source inventory at least annually to identify any sources that are not in routine use and have become disused. Disused sources should be included on the inventory of radioactive waste. The operator has the responsibility to meet any regulatory requirements for reporting disused sources. Once the radioactive sources have become disused, the operator should ensure the maintenance of continuity of control. The licensee will periodically review the status of control of such sources.

4.77. The following aspects should be considered in respect of the safe management of disused sealed radioactive sources (see also Appendix V):

(a) the further authorized use of the disused sealed radioactive source by another licensed operator;

(b) return of the source to the supplier;

(c) temporary storage in its original shielding for decay (for example for radionuclides with half-lives of less than 100 days);

(d) conditioning and processing (for example overpacking);

(e) long term storage (such as in a centralized storage facility) before conditioning and disposal

(f) disposal.

4.78. The most sustainable option for managing disused sealed sources is further use by another organization. If that is not possible, the preferred management option for disused sealed radioactive sources is the return of the source to its supplier. Unfortunately this option is not always available for many old (legacy) sources, as the original supplier may not be known, or no longer exists. For spent and disused sealed sources with short half-lives (for example, half-life not exceeding 100 days) and of high activity (for example, ^{192}Ir sources as used in medical applications and in gamma radiography), secure storage for decay may be the preferred option.

4.79. All disused sealed radioactive sources should be conditioned, unless the half-life of radionuclides contained in them is short enough to enable removal from regulatory control in a reasonably short period (for example two to three years). Long lived sources are generally conditioned in centralized radioactive waste management facilities by means of encapsulation in welded steel capsules to facilitate future management. Conditioning methods should be approved by the regulatory body (according to the national policy for radioactive waste management if it exists).

4.80. In instances where operators do not have facilities or expertise for conditioning of spent and disused sealed sources by encapsulation or adequate storage facilities, arrangements should be made to transfer the sources to another licensed organization with proper and adequate facilities (centralized conditioning or storage facility). Centralized facilities should be established for the safe long term storage of disused sealed radioactive sources containing Ra-226, Am-241 and other long lived radionuclides.

4.81. The management of disused sealed radioactive sources can involve potentially serious hazards. Sealed sources should not be subjected to compaction, shredding or incineration. As a general principle, the overriding need for safety means that sealed sources should not be removed from their primary containers, nor should the container be physically modified. Peripheral components of large irradiation equipment (those not directly associated with the source) should be removed, monitored and disposed of appropriately. A safety and environmental impact assessment should be carried out before any operations are undertaken. For sources (such as disused radium sources) with a potential for leakage particular radiological precautions should also be taken during the handling and storage. Special attention should be given to the monitoring of surface and airborne contamination. These sources should be stored in a dedicated area with appropriate ventilation and equipment (see Annex I).

4.82. The most important consideration in the management of sealed sources, once they are no longer useful, is the maintenance of continuity of control. Provisions should be made by the operator and regulatory body to maintain and revisit the status of control of such devises and material.

4.83. The regulatory body should pay attention to situation involving disused sealed sources, which cannot be returned to the supplier or manufacturer. Such sources may require subsequent management such as conditioning for which the operator is neither qualified nor licensed. While not strictly a responsibility of the regulatory body, it could be helpful if the Regulatory body gives consideration to the assignment and authorization of an appropriate organization, which is better equipped to safely conduct the necessary management operations.

Orphan sources

4.84. There have been many cases of sealed sources being acquired for specific purposes (such as industrial process control) and of subsequently being lost because the operating organization ceases operation and control over the sources has been lost. Many portable radiography devices contain valuable heavy metals and become attractive for scrap purposes. These are some of the reasons for disused sealed radioactive sources becoming lost from regulatory control. In order to address the issue of these 'orphan' sources countries should establish and implement an appropriate national strategy. An example of a strategy for identification and location of these types of sources is presented in Annex II.

4.85. In all cases the strategy should ensure that whenever an orphan source has been identified, appropriate recovery measures are taken (36). These should include identification of the responsible organizations and funding within the country to recover, handle, condition, store and if necessary dispose of the source as a radioactive waste according to the national policy and strategy for radioactive waste management.

Generation of radioactive waste from accidents or incidents

4.86. Loss or unauthorized use of radioactive materials (such as sealed sources) can give rise to accidents resulting in radiation exposure to workers, contamination of working premises and land, and exposure of members of the general public. This can lead to the unplanned and accidental generation of radioactive waste. Users and operators should take all appropriate measures to ensure that appropriate technical and organizational means are in place, including the necessary contingency arrangements for the processing and storage of any such accidentally generated radioactive waste.

On-site handling

4.87. Handling of radioactive waste on site includes all transfer (movement) operations from the source of generation to the processing, storage and/or disposal location. This may include physical handling, process flow or on-site transport (including loading and unloading of packages from conveyances). Handling should be carried out:

(a) in containers or with overpacks that are easily decontaminated;

(b) under adequate operational radiation protection control;

(c) with appropriate labelling of the radioactive waste package and vehicles; and

(d) in accordance with the site radiation protection programme, physical protection procedures, safe transport and emergency planning, as well as the standards established by the national legislation.

4.88. A survey for non-fixed surface radioactive contamination should be conducted before the package is handled. This serves to protect workers handling the package, helps prevent accidental spread of contamination, and provides an independent check of the record keeping system. In addition, a maximum allowable radiation dose rate at the surface of each radioactive waste package, or at a specified distance from the surface, should also have been defined as part of the package acceptance requirements for storage.

4.89. The unexpected presence of radioactive contamination on a radioactive waste package may be an indication that the package itself or one nearby has been breached or physically damaged. Preplanned and documented procedures should be available and followed in such an event. As a minimum, the area around the suspect packages should be confined, the person responsible for waste safety should be notified, and procedures implemented to identify the source of contamination and to ensure that it is contained. The simplest means of containing the source of contamination is, if possible, to place it in a secondary overpack container.

Off-site transport

4.90. Transport of radioactive waste should be carried out in accordance with national regulations and in compliance with the IAEA Transport Regulations [10, 11].

4.91. Prior to transport of radioactive waste packages from the sites on which they are generated, the necessary confirmation should be obtained that the waste will be accepted at its intended destination. The operator of the facility to which the waste is being transported should clearly specify to the user the safety related information and formal documentation that is needed for acceptance.

4.92. Information to be provided upon transfer of waste should include as a minimum for each individual package:

(a) comprehensive identification of the user;

(b) identification number of the package;

(c) type and design details of the package and unloading documentation;

(d) weight of package;

(e) external size and/or volume of the package;

(f) maximum dose rate at contact and at 1 m (transport index) and date of measurement;

(g) results of surface contamination measurements and date of measurement;

(h) radionuclide content and activity content;

(i) fissile material content (such as ^{239}Pu–Be sealed sources), if applicable;

(j) physical nature;

(k) origin of waste;

(l) presence of potential pathogenic, chemical, and other types of hazards;

(m) total number of drums or containers in the consignment; and

(n) total weight of the consignment.

4.93. All documentation corresponding to a waste package should be verified by a designated person prior to transportation, in order to ensure compliance with the waste acceptance requirements and any national transport regulation in addition to the IAEA Regulations for the Safe Transport of Radioactive Material [10].

4.94. In the case of sealed sources, shielding is usually an integral part of the original storage and/or transport package. The dimensions and type of shielding depend on activity and radionuclides to be shipped. If possible, the original manufacturer's packaging should be used in transporting the disused sealed radioactive sources. However, consideration should be given to whether the design of the original packaging is in compliance with the IAEA Transport Regulations and whether the package continues to meet its design standard. If the original package is not available, the disused sealed radioactive sources should be repackaged in accordance with the IAEA Transport Regulations [10].

STORAGE OF RADIOACTIVE WASTE

Requirement 11: Storage of radioactive waste

Waste shall be stored in such a manner that it can be inspected, monitored, retrieved and preserved in a condition suitable for its subsequent management. Due account shall be taken of the expected period of storage, and, to the extent possible, passive safety features shall be applied. For long term storage in particular, measures shall be taken to prevent degradation of the waste containment [3].

4.95. Within the context of radioactive waste management, storage refers to the temporary placement of radioactive waste in a facility where appropriate isolation and monitoring are provided. Storage takes place between and within the basic steps in the predisposal management of radioactive waste. Storage is used to facilitate the subsequent step in radioactive waste management; to act as a buffer between and within waste management steps; to await the decay of radionuclides prior to clearance or authorized discharge; or to hold waste generated in emergency situations pending decisions on its future management.

4.96. Prior to generating radioactive waste that may require subsequent management the operator should ensure the availability of an appropriate storage facility within his own organization, or in another authorized facility. The operator should follow the agreed national policy and strategy; whenever he has to define which type of waste have to be stored for authorized discharge, authorized use or clearance or for processing and/or disposal at a later time.

4.97. The operator should have arrangements in place to verify if the waste, collected or received in the storage facility under its responsibility meets the acceptance criteria approved by the regulatory body in the safety case for this facility. In defining criteria for acceptance of waste packages in a storage facility, the operator should take account of the known or likely requirements for subsequent disposal of the radioactive waste. In case the waste or sources to be stored do not meet the acceptance criteria, the operator will establish provisions which compensate for the non-compliance or refuse the transfer.

4.98. Provision should be made for the regular monitoring, inspection and maintenance of the waste and the storage facility to ensure their continued integrity and the subsequent management of the radioactive waste package. Due account need to be taken of the expected period of storage, and, to the extent possible, passive safety features need to be applied. For long term storage in particular, measures should be taken to prevent the degradation of the waste containment.

4.99. The design of the storage facility depends on the type of radioactive waste, its characteristics and associated hazards, the radioactive inventory, and the anticipated period of storage.

4.100. Storage is by definition an interim measure, but it can last for several decades. The intention in storing waste is that the waste can be retrieved for clearance, processing and/or disposal at a later time, or in the case of effluent for authorized discharge.

4.101. The adequacy of the storage capacity should be periodically reviewed, with account taken of the predicted waste arisings, both for normal operation and for possible incidents, the expected lifetime of the storage facility and the availability of disposal options.

4.102. Consideration should be given to the protection of present and future generations in accordance with the Fundamental Safety Principles (Principle 7) [2] when it is proposed to store radioactive waste for a long period of time.

4.103. Storage of radioactive waste may be necessary:

(a) for decay, prior to the removal of regulatory control;

(b) prior to pretreatment, treatment and conditioning; or

(c) prior to disposal or transfer to another authorized facility.

4.104. Radioactive waste should be stored in a manner that ensures isolation, protection of the workers, the public and the environment, and enables subsequent movement handling, transport or disposal. Full traceability of the waste packages by means of record keeping and adequate labelling should be maintained during storage.

4.105. The safety of storage arrangements should be ensured for any radioactive waste management activity. On-site storage may be used to allow decay to levels where control may be removed from the materials. Storage may be necessary for operational reasons (such as for unconditioned radioactive waste prior to subsequent conditioning or off-site transfer). In general, on-site storage period should be kept as short as practicable to ensure the long term safety of the waste. This is particularly so when the waste is to be transferred to a central storage facility for radioactive waste and when optimal longer term storage capabilities may not be available at the facility where the waste is generated. Storage facilities may be necessary for untreated, treated and conditioned radioactive waste. Special attention should be paid to the storage of unconditioned radioactive waste in order to limit any leakage from packages.

4.106. In considering arrangements for the storage of radioactive waste a detailed evaluation should be made of:

(a) the type and characteristics of the radioactive waste;

(b) the original integrity of the waste packages and potential levels of surface contamination;

(c) the closure and/or sealing of the packages and their continued integrity under storage conditions;

(d) the envisaged storage period and possibility of further extension;

(e) ability to comply with handling, storage and physical protection criteria;

(f) need and type of monitoring e.g. airborne radioactive substances in the storage facility; and

(g) possibility of identification of potential damage to waste packages and facilitating of respective corrective measures.

4.107. If according to the National Policy and Strategy radioactive waste is to be stored in a centralized storage facility[6], the operator should adopt provisions to ensure the prompt transfer of above waste and disused sources to that facility.

---

[6] A centralized facility is a facility in which radioactive waste originating from many generators is managed.

4.108. Detailed guidance on design and operation of small storage facilities for radioactive waste is provided in Ref. [9].

Storage prior to discharge or removal of regulatory control

4.109. Storage for decay is particularly important for the clearance of radioactive waste containing short lived radionuclides. As was mentioned before, clearance is the removal of radioactive material from regulatory control provided that the radionuclide concentrations are below radionuclide specific clearance levels. Many radionuclides in use, particularly in research and medical applications have half-lives ranging from a few hours to a few months.

4.110. The decay storage period should be long enough to reduce the initial activity to levels lower than the clearance levels. The decay storage period strongly depends of the initial activity of the radionuclide this is why in every case a calculation should be performed in order to determine the proper decay storage period. Practical experience shows that storage for decay is usually suitable for all types of radioactive waste, solid, liquid and gaseous containing radionuclides with half-lives no greater than about 100 days. For example, radioactive waste from nuclear medicine, such as excreta containing ^{99m}Tc (half-life about 6 h), may be stored for decay and subsequent discharge. Nevertheless, waste with longer half-lives may also be safely stored for decay to insignificant levels and considerations should be given to such waste on a case-by-case basis. Generic clearance levels and guidance for the derivation of clearance levels are provided in Ref [6, 12].

4.111. From safety, technical and economic points of view storage for decay, where appropriate, is the preferred management option for radioactive waste generated in medical, industrial and research activities. Relatively small volumes of radioactive waste, contaminated with short lived radionuclides, with suitable activity content or activity concentration, should be collected and stored safely for sufficient time until the waste meets the regulatory criteria for removal (clearance) of the material from a regulated facility or activity or authorized discharge.

4.112. Storage of radioactive waste for decay and subsequent removal of regulatory control needs rigorous administrative control measures. Activity should be carefully measured and waste should be segregated, both at the point of generation and at the end of the decay storage period. Representative measurements should be carried out or samples taken and analysed prior to removal of each batch from control. In taking samples, consideration should be given to the protection of workers against radiological and non-radiological risks.

4.113. There should be rigorous control measures for the storage of radioactive waste for decay and its subsequent removal from regulatory control. The activity concentration of the waste should be carefully determined and such waste designated for decay should be segregated from other waste, from the point of generation up to the end of the decay storage period and its disposal. Representative measurements should be carried out on samples taken and analysed prior to the removal of each batch from control. In taking samples, workers should be protected against both radiological and non-radiological hazards.

4.114. While storage for decay is also the preferred option for biohazardous radioactive waste and for other perishable waste such as animal carcasses, such wastes should be segregated and stored in a freezer or refrigerator cabinet for decay storage. Decayed biohazardous radioactive waste should not be disposed of in a landfill site unless specific approval has been obtained from the regulatory body. Incineration of such waste is usually the preferred option; further guidance should be sought from the relevant competent body concerning the conditions under which such waste can safely be incinerated.

4.115. Record should be kept and retained of any cleared or released radioactive material.

Storage prior to processing

4.116. Each package should be tracked while in storage to facilitate its retrieval for further processing. Adequate radiological protection controls and physical security should be provided and the storage period of unconditioned waste should be limited, as unconditioned radioactive waste may present unexpected hazards. The waste should be stored in a way that ensures:

(a) storage of packages in specially designated areas, premises, or specifically constructed facilities (on-site or centralized facilities);

(b) compliance with the acceptance criteria for waste storage;

(c) control of packages on receipt (such as control of the integrity of the waste package, surface contamination and compliance with the supporting documentation);

(d) separate storage of different waste types (including mixed waste) according to the presence of pathogenic, organic, toxic or other waste;

(e) reliable labelling of packages; and

(f) tracking of the current status of waste and availability of supporting documentation.

Storage of radioactive waste prior to disposal

4.117. Treated and conditioned radioactive waste should be stored separately from unconditioned waste, inactive raw materials and maintenance materials. The packages should be stored for example in bins, racks, pallets or skids for efficiency. Storage locations should be planned so as to minimize handling and transport.

4.118. Conditioned radioactive waste should be stored in a safe and physically secure manner after processing, and prior to transfer to a disposal facility.

4.119. The storage proposals should be considered in the safety and environmental impact assessment to demonstrate the acceptability of the proposed design and operational arrangements. The safety objectives during storage should ensure that stored waste will remain adequately contained, that radiation from the stored waste is adequately shielded and that the stored packages will not degrade and give rise to future problems in handling and disposal.

4.120. In some cases, an central storage or disposal facility is not yet in place. Although the need for radiotherapy and other medical, industrial and research activities continues, ultimate disposition of the attendant waste is not yet possible. In these cases, such operations may not be able to comply fully with all the recommendations in this section. This guidance endeavours to assist those responsible for safety to design a radioactive waste management programme, which provides for the protection of health and the environment to the extent achievable.

4.121. Detailed safety recommendations on storage of radioactive waste could be found in Reference [9].

RADIOACTIVE WASTE ACCEPTANCE CRITERIA

Requirement 12: Radioactive waste acceptance criteria

Waste packages and unpackaged waste that are accepted for processing, storage and/or disposal shall conform to criteria that are consistent with the safety case [3].

4.122. The interdependence among the steps in the management of radioactive waste needs to be considered for achieving continuity in operations and consistency of the entire waste management process.

4.123. The operator of a particular waste predisposal management step or disposal facility needs to define in the safety case its own waste acceptance criteria bearing in mind the criteria established for other steps within the waste management process. Waste acceptance criteria and/or requirements should be developed that specify the radiological, mechanical, physical, chemical and biological characteristics of waste packages and unpackaged waste that are to be processed, stored or disposed of; for example, their radionuclide content or activity limits, their heat output and the properties of the waste form and packaging. Each criterion established by the operator of a facility should be submitted to the regulatory body for review, assessment and approval as part of the safety case.

4.124. Adherence to the waste acceptance criteria and/or requirements is necessary for the safe handling and storage of waste packages and unpackaged waste during normal operation, for safety during possible accident conditions and for the long term safety of the subsequent disposal of the waste. The operator should ensure that an appropriate control system is established to provide confidence that the waste under its responsibility meets the applicable acceptance criteria and/or requirements.

4.125. The operator ensures that radioactive waste to be transferred to other installations or waste management steps meets the waste acceptance criteria established by the operator of the subsequent step.

4.126. The operators' procedures for the reception of waste have to contain provisions for safely managing waste that fails to meet the acceptance criteria; for example, by taking remedial actions or by returning the waste in compliance with transport regulations..

4.127. Radioactive waste should only be disposed of in facilities licensed to accept the type of waste in question. National disposal facilities for radioactive waste should be designated as part of the national policy and strategy for radioactive waste management [7].

4.128. The operator of a waste disposal facility should establish specific acceptance requirements and procedures, approved by the regulatory body, for different types of radioactive waste and packages and should make them available to users. The radioactive waste should comply with waste acceptance requirements that address:

(a) the extent of waste processing (stable form and container resistance);

(b) the maximum content of liquid (usually up to 1% in the total radioactive waste volume);

(c) the mechanical, chemical, structural, radiological, biological stability of the waste form;

(d) the limitation of activity (for example, activity per package);

(e) the absence of a potential for criticality;

(f) the extent to which the waste should be of non-pyrophoric, explosive or reactive;

(g) the possibility of generation of toxic gases; and

(h) the limitation of heat generation.

4.129. The operator of the disposal facility should also clearly identify the documentation to be provided by the waste supplier, as well as the relevant waste package records. Waste packages should be inspected on an appropriate manner either prior to the shipment to a disposal facility or on receipt at the disposal facility. Caution should be applied to the receipt of all packages, as they may not be in compliance with the agreed specification and associated documentation. Inspection should include verification of:

(a) the number of packages and respective identification;

(b) physical integrity of the package;

(c) surface contamination levels;

(d) external dose rate of the package; and

(e) completeness of documentation.

4.130. Upon receipt, full confirmation of the content of the package should be carried out without compromising the integrity of the package. The information received from the user (supplier) and the data obtained as part of the receipt control should be recorded.

5. SAFETY CASE AND SAFETY ASSESSMENT

GENERAL

5.1. "The results and findings of the safety assessment are to be documented, as appropriate, in the form of a safety report that reflects the complexity of the facility or activity and the radiation risks associated with it. The safety report presents the assessments and the analyses that have been carried out for the purpose of demonstrating that the facility or activity is in compliance with the fundamental safety principles and the requirements established in Ref. [33], and any other safety requirements as established in national laws and regulations" para. 4.62, Ref. [33].

5.2. Safety assessment is the main component of the safety case and involves assessment of a number of aspects. The fundamental element of the safety assessment is the assessment of the radiological impact on humans and the environment in terms of both radiation dose and radiation risks. The other important aspects subject to safety assessment are site and engineering aspects, operational safety, non-radiological impacts and the management system.

5.3. A specific role of the safety case in aiding decision making about processing options is to ensure that suitable waste forms are produced. The safety case should provide an integrated consideration of safety for all waste management steps, and should address both the safety of operations at the individual facility and the interdependencies with other waste management steps. The adequacy of waste forms produced should be judged on the basis of waste acceptance criteria for all subsequent waste management activities, in particular processing, storage, transport and eventual disposal of the waste. There are many aspects connected to these decisions, some of which will be based on quantitative assessments while others will be more qualitative in nature.

5.4. The safety case is of particular importance and benefits for large predisposal waste management facilities, such as centralized facilities for the processing and storage of radioactive waste in States that have a nuclear power programme. For smaller scale facilities, such as storage facilities for disused sealed sources, the components of the safety case are still relevant; however the level of detail and the complexity and depth of the safety assessment are required to be commensurate with the potential hazard Ref. [33]. In addition the actual process of developing the safety case and supporting safety assessment will be commensurately less demanding, and several of the aspects discussed below, such as development of the safety case in stages, will be less relevant for some types and sizes of facilities. This is an expression of the graded approach described in [4, 6]. Detailed description of the safety assessment and safety case are given in the Safety Guide on “The Safety Case and Safety Assessment for Predisposal Management of Radioactive Waste” [15]. IAEA Safety Reports setting out examples of safety cases are under development to provide additional guidance on the level of depth and detail warranted for safety cases prepared for smaller facilities.

APPROACH TO SAFETY

5.5. Any application for authorization needs to include a safety case and supporting safety assessment and environmental assessments as required. The information that is supplied should reflect the requirements of the regulatory body and should be commensurate with the complexity of the facility and its potential impacts.

5.6. Wherever practical, waste management practices should be covered by the authorization for the operation or facility which gives rise to the waste. For example, management of radioactive waste at a nuclear medicine operation could be included in the authorization to conduct nuclear medicine activities.

PREPARATION OF THE SAFETY CASE AND SUPPORTING SAFETY ASSESSMENT

Requirement 13: Preparation of the safety case and supporting safety assessment

The operator shall prepare a safety case and a supporting safety assessment. In the case of a step by step development, or in the event of modification of the facility or activity, the safety case and its supporting safety assessment shall be reviewed and updated as necessary [3].

5.7. The safety case has to be prepared by the operator early in the development of a facility as a basis for the process of regulatory decision making and approval. The safety case has to be progressively developed and refined as the project proceeds. Such an approach ensures the quality of the technical programme and the associated decision making. It is the operator’s responsibility to compile the safety assessment as part of the safety case in accordance with the requirements of the regulatory body.

5.8. The safety case provides a framework in which confidence in the technical feasibility and safety of the facility can be established at each stage of its development. This confidence is developed and enhanced by means of iterative design studies and safety studies as the project progresses. The step by step approach provides for the collection, analysis and interpretation of the relevant technical data, the development of plans for design and operation, and the development of the safety case for operational safety.

SCOPE OF THE SAFETY CASE AND SUPPORTING SAFETY ASSESSMENT

Requirement 14: Scope of the safety case and supporting safety assessment

The safety case for a predisposal radioactive waste management facility shall include a description of how all the safety aspects of the site, the design, operation, shutdown and decommissioning of the facility and the managerial controls satisfy the regulatory requirements. The safety case and its supporting safety assessment shall demonstrate the level of protection provided and shall provide assurance to the regulatory body that safety requirements will be met [3].

5.9. The regulatory body establishes requirements for persons or organizations responsible for facilities and activities that give rise to radiation risks to conduct an appropriate safety assessment. Prior to the granting of an authorization, the responsible person or organization is required to submit a safety assessment, which is reviewed and assessed by the regulatory body.

5.10. Safety assessments should be conducted at different stages, including the stages of siting, design, construction, commissioning, operation, and decommissioning of facilities or parts thereof, as appropriate, so as:

(a) To identify the ways in which exposures could be incurred, account being taken of the effects of external events as well as of events directly involving the sources and associated equipment;

(b) To determine the expected magnitudes and likelihood of exposures in normal operation and, to the extent reasonable and practicable, make an assessment of potential exposures; and

(c) To assess the adequacy of the provisions for protection and safety.

5.11. The safety case has to address operational safety and all safety aspects of the facility and activities. The safety case has to include considerations for reducing hazards posed to workers, members of the public and the environment during normal operation and in possible accident conditions [3].

5.12. The design of the facility, the arrangements for operational management and the systems and processes that are used should be considered and justified in the safety case. This will involve the identification of waste arising and the establishment of an optimal programme of waste management to minimize the amount of waste generated and to determine the design basis and operational basis for the treatment of effluents, the control of discharges and clearance procedures. Its primary aim is to ensure that the safety objectives and criteria set by the regulatory body are met.

5.13. The safety assessment should include, as appropriate, a systematic critical review of:

(a) The operational limits and conditions for the operation of a facility;

(b) The ways in which structures, systems and components, including software, and procedures relating to protection and safety might fail, singly or in combination, or might otherwise give rise to exposures, and the consequences of such events;

(c) The ways in which external factors could affect protection and safety;

(d) The ways in which operating procedures relating to protection and safety might be erroneous, and the consequences of such errors;

(e) The implications for protection and safety of any modifications;

(f) The implications for protection and safety of security measures or of any modifications to security measures; and

(g) Any uncertainties or assumptions and their implications for protection and safety.

5.14. The operator should take into account in the safety assessment:

(a) Factors that could precipitate a substantial release of radioactive material, the measures available to prevent or to control such a release, and the maximum activity of radioactive material that, in the event of a major failure of the containment, could be released to the environment;

(b) Factors that could precipitate a smaller but continuing release of radioactive material, and the measures available to detect and to prevent or to control such a release;

(c) Factors that could give rise to unintended operation of any radiation generator or a loss of shielding, and the measures available to detect and to prevent or control such occurrences;

(d) The extent to which the use of redundant and diverse safety features, which are independent of each other so that failure of one does not result in failure of any other, is appropriate to restrict the likelihood and the magnitude of potential exposure.

5.15. The extent and detail of the safety case and the safety assessment should be commensurate with the complexity of the operations and the magnitude of the hazards associated with the facility and activities. In relation to waste management the safety case should address the following:

(a) chemical, physical and radiological properties of the waste to be generated;

(b) radioactive waste management strategy (programme) which includes: 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 description of facilities and their associated systems;

(c) safety assessment of the activities and facilities and thus, a demonstration of the integrity of the facility and the associate waste control measures;

(d) a demonstration of compliance with established safety criteria and regulations in force;

(e) storage arrangements;

(f) arrangements for removal (clearance) of regulatory control from materials, activities and facilities, if permitted in the national regulations;

(g) arrangements for waste to be removed from the site for storage, processing or disposal at some other site;

(h) discharge proposals (points and method of discharge and related controls);

(i) discharge and environmental monitoring programmes and safety assessment proposals;

(j) decommissioning plans and procedures;

(k) radiation protection programme and evidences of the optimization of radiation protection;

(l) description of the management system including operational procedures and record keeping;

(m) staff competence and training provisions; and

(n) emergency plan in the event of an accident which involves radioactive waste.

5.16. Safety assessment should demonstrate that the performance objectives of the waste management facility and the processes used can be satisfied and that the overall system is acceptable for licensing or authorization. The resulting information should include predicted impacts on the workers, the public and the environment. The quantities and concentrations of radioactive or other hazardous materials that may be safely discharged from the facility should be determined and documented. The extent of the safety assessment depends on the propensity for risk (severity of harm posed by the hazard and the likelihood of harm) to the workforce, public and environment from the proposed operations. The focus of safety assessment for users or operators managing lesser quantities of waste should be on demonstrating compliance with regulatory requirements.

5.17. The safety assessment should be independently reviewed under the relevant management system.

5.18. Non radiological environmental impact assessment is usually carried out in accordance to national environmental laws and regulations and is outside the scope of this Safety Guide.

5.19. A systematic and structured approach to the assessment should be demonstrated, with account taken of all stages in the waste management process, both as individual stages, and as a part of an integrated waste management system. For simpler and smaller operations this integrated waste management system may be fairly straightforward and brief. The assessment process should include interdependences between stages of waste management and between the organizations involved. It should also consider normal and abnormal operating conditions and propose actions to reduce identified risks to an acceptable level, in compliance with the requirements of the regulatory body.

5.20. Where complex and elaborate waste management operations are proposed, it may be appropriate to apply sophisticated hazard analysis. However, for the majority of small users and/or operators, a simplified assessment approach should be adequate. An example of a fault schedule for such an assessment is given in Appendix II. The purpose of the fault schedule is to identify hazards to operators and to propose engineered, administrative and contingency controls to result in an acceptable risk. Risks should be categorized both from radiological and non-radiological perspectives.

5.21. The results of the safety assessment are normally assembled as a report. The report should address both radiological and non-radiological risks which may arise under normal and abnormal conditions, and actions to be taken to reduce these risks to acceptable levels. The arrangements for such actions, which include reference levels, conditions, practical and administrative procedures, should form the basis of operational documentation which should be implemented by the user or operator. Details on the safety assessment process and content of the safety case for predisposal waste management facilities are given in Ref. [15, 33].

DOCUMENTATION OF THE SAFETY CASE AND SUPPORTING SAFETY ASSESSMENT

Requirement 15: Documentation of the safety case and supporting safety assessment

The safety case and its supporting safety assessment shall be documented at a level of detail and to a quality sufficient to demonstrate safety, to support the decision at each stage and to allow for the independent review and approval of the safety case and safety assessment. The documentation shall be clearly written and shall include arguments justifying the approaches taken in the safety case on the basis of information that is traceable [3].

5.22. Justification involves explaining why particular choices were made and stating the arguments in favour of and against the decisions made, especially those decisions that relate to the main approaches taken in the safety case.

5.23. Traceability refers to the possibility of following the information that is in the documentation and that has been used in developing the safety case. For the purposes of both justification and traceability, a well documented record is necessary of the decisions and assumptions that were made in the development and operation of the facility, and of the models and data used in the safety assessment to obtain the set of results. Good traceability is important for the purposes of technical and regulatory review and for building public confidence.

5.24. Clarity refers to good structure and presentation at an appropriate level of detail such as to allow an understanding of the arguments included in the safety case. This necessitates that the documents present the work in such a way that the interested parties for whom the documents are intended can gain a good understanding of the safety arguments and their bases. Different styles and levels of documentation may be necessary, depending on the intended audience for the material.

PERIODIC SAFETY REVIEWS

Requirement 16: Periodic safety reviews

The operator shall carry out periodic safety reviews and shall implement any safety upgrades required by the regulatory body following this review. The results of the periodic safety review shall be reflected in the updated version of the safety case for the facility [3].

5.25. The operator must periodically review the safety assessment in order to confirm that any input assumptions requiring compliance remain adequately controlled within the overall safety management controls.

5.26. The safety assessment and the management systems within which it is conducted should be periodically reviewed at predefined intervals in accordance with regulatory requirements. In addition to such predefined periodic reviews, the safety assessment should be reviewed and updated:

- When there is any significant change that may affect the safety of the facility or activity;

– When there are significant developments in knowledge and understanding (such as developments arising from research or operational feedback experience);

– When there is an emerging safety issue owing to a regulatory concern or an incident;

– When there have been significant improvements in assessment techniques such as computer codes or input data used in the safety analysis.

5.27. If as a result of a safety assessment, or for any other reason, opportunities to improve protection and safety appear to be available and improvement seems desirable, any consequential modifications need to be made cautiously and only after favourable assessment of all the implications for protection and safety. The implementation of all improvements needs to be prioritized so as to optimize protection and safety.

6. DEVELOPMENT AND OPERATION OF PREDISPOSAL RADIOACTIVE WASTE MANAGEMENT FACILITIES AND ACTIVITIES

GENERAL

6.1. The development of authorizations and of limits, conditions and controls for the predisposal management of radioactive waste benefits from close communication and cooperation between the operators, regulatory bodies and other interested parties.

6.2. It is the responsibility of the regulatory body to derive and document in a clear and unambiguous manner the criteria on which the regulatory decision making process is based. It is important that any additional guidance provided by the regulatory body takes account of the wide range of predisposal radioactive waste management facilities that may be developed and the wide range of activities that may be conducted at these facilities.

6.3. The safety of predisposal radioactive waste management facilities should be ensured through the use of good engineering and management practice. In particular the defence in depth principle, providing for multiple levels of protection against failures both for technical reasons or human errors should be adopted. This should include:

(a) multibarrier systems of several physical barriers on the migration pathway of the radionuclides to the environment;

(b) technical and organizational means for protection of the integrity and efficiency of the barriers; and

(c) measures for protection of the public and environment in case of failure of or damage to the barriers.

6.4. At all stages of the life cycle of radioactive waste management facilities (siting, design, commissioning, operation, closure, decommissioning) technical and organizational means to apply the defence in depth principle should be provided with regard to the following three aspects:

(a) measures to prevent deviation from the normal operation;

(b) measures to prevent accidents and mitigate consequences; and

(c) measures for emergency planning.

LOCATION AND DESIGN OF FACILITIES

Requirement 17: Location and design of facilities

Predisposal radioactive waste management facilities shall be located and designed so as to ensure safety for the expected operating lifetime under both normal and possible accident conditions, and for their decommissioning [3].

6.5. The features to be incorporated in the design depend largely on the properties, total inventory and potential radiological and non-radiological hazards associated with the radioactive waste that is to be managed and on the requirements of the regulatory body.

6.6. The need for operational maintenance, testing, examination and inspection should be addressed from the conceptual design stage onward.

6.7. In designing facilities for processing radioactive waste, consideration should be given to providing:

(a) separation of the radioactive waste processing systems from the other systems, as well as from the premises and facilities, where other potentially hazardous materials are stored;

(b) auxiliary systems, for example for sampling or decontamination;

(c) radiological control at all stages including control over waste receipt, and elements affecting personnel protection and protection of the working environment;

(d) adequate containment (e.g. fume cupboards, drip trays, sealed and dipped work benches) and shielding (e.g. lead or concrete blocks);

(e) for demarcation of the working premises according to their classification (e.g. labels, rope or other barriers) for area and personnel, as adequate;

(f) for radiation control (dose rate and surface contamination measurement);

(g) technological control, such as recording of radioactive waste characteristics and control over the characteristics of the final product (radioactive waste form);

(h) arrangements for the location and layout of the equipment and systems in a way that provides ease of access for normal operation, maintenance, and control;

(i) for the safe handling of waste by having appropriate handling equipment and selecting short and uncomplicated routes;

(j) easily decontaminable surfaces;

(k) adequate drainage and ventilation systems (e.g. air filtration, air pressure differentials and flow considerations);

(l) normal and emergency electrical supplies;

(m) premises for emergency equipment;

(n) fire protection systems; and

(o) physical protection.

6.8. Depending on the quantities of radioactive waste to be processed and/or stored, safety arrangements can range from processing and/or storage in a shielded cabinet to dedicated separate rooms or facilities. The specific arrangements depend largely on the activities, chemical and physical characteristics of the radioactive waste and the amounts involved, as well as on the technologies available. The requirement to maintain radiation doses as low as reasonably achievable and the preference for maintaining working areas free of radioactive waste with long half-lives may mean that a small separate room should be provided where the waste can be stored in an orderly way. However, where only very small amounts of radioactive waste are produced over many days of work, a local store or cabinet close to the workplace may be used.

6.9. In general, containers should be suitable for the safe management of the specific waste, and selected according to the chemical and radiological characteristics of the waste, the volume, and the handling and storage specifications. Pressurization of the containers due to the expansion of liquids and the generation of gases and vapours (mainly when handling organic fluids) should be avoided.

6.10. The design of storage facilities should allow for regular inspection and monitoring, including radiation control (dose rate and surface contamination) and visual examination of waste packages in order to obtain an early indication of any physical deterioration or leakage. The lifetime of the construction materials should correspond to the envisaged storage period and should ensure that the storage conditions are such as to maintain the characteristics of the waste packages for the designed storage period. The design of the storage facility should ensure: the possible future extension of the storage period and the possible removal of the radioactive waste from the facility for subsequent processing or disposal.

CONSTRUCTION AND COMMISSIONING OF THE FACILITIES

Requirement 18: Construction and commissioning of the facilities

Predisposal radioactive waste management facilities shall be constructed in accordance with the design as described in the safety case and approved by the regulatory body. Commissioning of the facility shall be carried out to verify that the equipment, structures, systems and components, and the facility as a whole, perform as planned [3].

6.11. It is the responsibility of the operator to construct facilities in accordance with the approved design, including conducting any verification tests that need to be performed (e.g. the testing of welds or foundations). The regulatory body is responsible to assure that the operator constructs the facility in accordance with an approved design, and that the operator conducts approved construction verification activities.

6.12. Commissioning may be carried out in several stages that are subject to the review and approval of the regulatory body. In larger, more complex facilities the following stages are normally performed: completion of construction and inspection, installation and testing of equipment, demonstration of performance, non-active (i.e. without radioactive waste) commissioning and active (i.e. with radioactive waste) commissioning.

6.13. Upon the completion of commissioning, a final commissioning report is usually produced by the operator. The report should document the as-built status of the facility, which, in addition to providing information to facilitate operation, is important when considering possible future modifications to the facility and its shutdown and decommissioning. The report should describe all the testing and should provide evidence of the successful completion of testing and of any modifications made to the facility or to procedures in commissioning. The report should provide assurance that all the conditions of authorization have been satisfied. This report should be maintained with the operator as part of the documentation needed for operation and for the development of the decommissioning plan. The regulatory body should assesse this report to ensure that all conditions and requirements are satisfied before agreeing to the operation of the facility. The safety case should be updated, as necessary, to reflect the as-built status of the facility and the conclusions of the commissioning report.

6.14. A modification of a facility with significant safety implications that requires a revision of the safety case should be subject to the same regulatory controls and approvals as applicable to the new facility.

FACILITY OPERATION

Requirement 19: Facility operation

Predisposal radioactive waste management facilities shall be operated in accordance with national regulations and with the conditions imposed by the regulatory body. Operations shall be based on documented procedures. Due consideration shall be given to the maintenance of the facility to ensure its safe performance. Emergency preparedness and response plans, if developed by the operator, are subject to the approval of the regulatory body [3].

6.15. The operator applying for a license to operate any facility for predisposal management of radioactive waste need to demonstrate to regulatory body that the conception of the facility is consistent with the agreed national policy and strategy if one exists. The operator should ensure that the facility for predisposal management of radioactive waste has sufficient capacity to process and store all such waste demanded by technological requirements of the installation or by the national policy and strategy.

6.16. The operational limits and conditions as well as administrative controls are not in all cases provided in the authorization document, but they may be given in a separate document (sometimes called the safety related technical specifications), referred to in the authorization document. All operations and activities important to safety are subjected to documented limits, conditions and controls, and are carried out by trained, qualified and competent personnel.

6.17. All facility specific, safety related criteria and documented operating procedures required by the regulatory body should be submitted to the regulatory body for approval. Such procedures may include a programme of periodic maintenance, testing and inspection of systems that are essential to safe operation, such as ventilation and sewage systems.

6.18. The operator applying for a license to operate large and/or centralized storage facility should design and construct a facility which:

(a) has sufficient storage capacity to account for uncertainties in the availability of facilities for treatment, conditioning and disposal. The design of a facility should take into account the possible need to process waste arising from incidents or accidents;

(b) is suitable for the expected period of storage, preferably using passive safety features, considering the potential degradation and with due consideration of natural site characteristics that could impact performance as geology, hydrology and climate;

(c) allows waste can be inspected, monitored and preserved in a condition suitable for release or transport, as appropriate;

(d) ensures appropriate containment of the waste; for example, on the integrity of the facility's structures and equipment, as well as the integrity of the waste forms and containers over the expected duration of storage. Consideration should be given to interactions between the waste, the containers and their environment (e.g. corrosion processes due to chemical or galvanic reactions); and

(e) makes provision for retrieval of the waste whenever required.

SHUTDOWN AND DECOMMISSIONING OF FACILITIES

Requirement 20: Shutdown and decommissioning of facilities

The operator shall develop, in the design stage, an initial plan for the shutdown and decommissioning of the predisposal radioactive waste management facility and shall periodically update it throughout the operational period. The decommissioning of the facility shall be carried out on the basis of the final decommissioning plan, as approved by the regulatory body. In addition, assurance shall be provided that sufficient funds will be available to carry out shutdown and decommissioning [3].

6.19. The objective of planning for decommissioning is to limit occupational exposures, the generation of waste and the potential for accidents during decommissioning [13, 14].

6.20. Facilities have to be shut down and decommissioned in accordance with the conditions set by the regulatory body. The objective is to facilitate the future dismantling activities, reducing occupational exposures, minimizing the generation of waste and reducing the potential for accidents during decommissioning. Particular consideration is given to any transfer of responsibility for the facility that may occur at this stage [13].

6.21. The time periods between updates to the decommissioning plan are dependent on the type of facility and the operational history and have to be agreed with the regulatory body [3].

6.22. Operators should give consideration to aspects of decommissioning of the facility at every stage of the facility's life cycle. This is particularly the case in respect of facility design and any subsequent modification. Also when decommissioning operations commence it should be ensured that the necessary administrative and managerial controls will remain in place or will be changed to accommodate the new circumstances. In principle, dismantling of processing or storage facilities should commence only after:

(a) radioactive waste and other potentially hazardous materials have been removed;

(b) the systems and components to be dismantled have been decontaminated.

However, acceptable safety cases may be envisaged, where not all waste is removed before decontamination and dismantling.

6.23. In arrangements for decommissioning, the following stages should be considered:

– Stage 1: justification and feasibility study including the characterization of the facility in order to define the decommissioning goal and whether it involves the removal of all radioactive material.

– Stage 2: source removal, involving removal of contained radioactive waste, disused sealed sources and sources of radioactive material;

– Stage 3: decontamination, including removal or reduction of contamination of materials, items, buildings and areas of the facility;

– Stage 4: dismantling, essentially reduction in size of the objects and components of the facility to facilitate their management (decontamination, handling) and subsequent removal from the site;

– Stage 5: final radiation survey, a systematic radiation survey of the decommissioned facility to ensure that the radiation protection objectives have been fulfilled;

– Stage 6: depending on the radiological conditions of the facility and decommissioning goal, the facility can be left to unrestricted use or use with restrictions and/or surveillance requirements may have to be implemented by the owner.

6.24. It should also be borne in mind that there may be a need for extended storage of waste arising from the decommissioning activities. The decommissioning activities could be combined depending on the type and scale of the processing or storage facility, the radioactive waste, as well as on the national strategy and availability of centralized storage and disposal facilities. Further requirements and guidance is provided in Ref [13, 14].

EXISTING FACILITIES

Requirement 22: Existing facilities

The safety at existing facilities shall be reviewed to verify compliance with requirements. Safety related upgrades shall be made by the operator in line with national policies and as required by the regulatory body [3].

6.25. The operator should cooperate with the regulatory body to establish a reasonable time frame to take the necessary measures to come into compliance.

6.26. The recommendations given in this publication are intended to apply to all facilities considered in the scope of this document. Since existing facilities might not be in compliance with all the requirements [3] and recommendations, decisions need to be taken, in line with national policies, with regard to the safety of these facilities. In such a case a review initiated by the regulatory body is used to identify those facilities that are not in compliance with all the requirements and that need additional modifications, operational restrictions, or to be shut down.

7. MANAGEMENT SYSTEMS

Requirement 7: Management systems

Management systems shall be applied for all steps and elements of the predisposal management of radioactive waste [3].

7.1. To ensure the safety of predisposal radioactive waste management facilities and the fulfilment of waste acceptance criteria, management systems are applied to the siting, design, construction, operation, maintenance, shutdown and decommissioning of such facilities and to all aspects of processing, handling and storage of waste. Features that are important to safe operation, and that are considered in the management system, are identified on the basis of the safety case and the assessment of environmental impacts [2, 27, 28, 34]. These activities are supported by means of an effective management system that establishes and maintains a strong safety culture [27, 28, 34].

7.2. Good management is a prerequisite to ensuring the safety of radioactive waste management and the protection of human health and the environment [6]. In the type of activities under consideration in this Safety Guide, where radioactive waste management may not be one of the higher management priorities, the application of good management practice should not be overlooked. Management and demonstration of quality in the waste management programme should be achieved by establishing and working within a formalized management system programme. The extent of the programme should be commensurate with the complexity of the activities undertaken, the waste generated and with the waste management programme.

7.3. Management system should be applied equally by the users, operators of waste management facilities and the regulatory body.

7.4. Important elements of the management system include, but are not necessarily limited to:

(a) definition of management structure and responsibilities;

(b) development of formal working procedures;

(c) training and qualification of staff;

(d) design control, performance standards;

(e) procurement of materials and services;

(f) document control and records;

(g) inspection, testing and maintenance;

(h) non-conformance control and corrective actions; and

(i) methods of assessment (internal and external auditing).

7.5. Every user or operator should establish and implement a management system that ensures:

(a) effective organization of all activities, related to the radioactive waste management and the operation, maintenance, and control of the systems, according to the design characteristics;

(b) maintenance of a record, control and record keeping of the documentation relating to the radioactive waste management and the associated facilities;

(c) control over compliance of the waste management activities with applicable standards and recommendations for radiation protection and safety;

(d) elaboration and implementation of internal procedures, instructions and programmes on radioactive waste management to ensure compliance with the requirements for radiation protection and safety.

7.6. Management and demonstration of quality is achieved by establishing and working to a formalized programme with an appropriate related management system approved by the regulatory body. The management system should be commensurate with the complexity of the activities undertaken and with the waste management programme. The management system should ensure compliance of the activities in radioactive waste management with conditions for authorization and should facilitate the provision of information to the regulatory body.

7.7. Guidance is given on the detailed components of management system programmes as part of an overall approach to quality management in Ref. [28, 34].

7.8. The user and operator should audit the implementation of the management system programme in its organization on a regular basis. Whenever deviations are identified, appropriate corrective actions should be proposed, taken and recorded.

7.9. The auditing should include revision of the quality assurance procedures to remove unwarranted complex procedures which do not contribute to safety with the confines of the licensed activity.

RECORD KEEPING AND REPORTING

7.10. A suitable and comprehensive recording system should be developed as part of the management system for radioactive waste management activities. Information on waste inventories should be properly recorded, updated (such as changes to waste characteristics during processing), transferred (between waste management stages or to another responsible organization) and retained in such a way as to ensure that relevant information is accessible in the future, as necessary.

7.11. The person responsible for the safety of radioactive waste management should review on a regular basis the proper functioning of the record system. Safety related details of history of disused sealed sources, considered as waste, should be included in the inventory. The record system should allow for traceability of waste from the point of its collection through to long term storage and/or disposal;

7.12. Users and operators should ensure that record keeping of data relating to the main radioactive waste characteristics is adequately maintained and retained for:

(a) source of origin;

(b) physical and chemical form

(c) amount (volume and/or weight);

(d) radiological properties (the activity concentration, the total activity, the radionuclides present and their relative proportions including date of measurement);

(e) physical and chemical properties;

(f) categorization in accordance with the categorization scheme for operational purposes

(g) classification in accordance with the national waste classification system;

(h) thermal properties, when applicable;

(i) any chemical, pathogenic or other non-radiological hazard associated with the waste and the concentration of hazardous material; and

(j) any special handling necessary owing to criticality concerns, the need for the removal of decay heat or significantly elevated radiation fields.

7.13. The operator of a facility generating radioactive waste, in order to ensure the proper control under waste management activities, should maintain records for:

(a) Generated radioactive waste (date of generation, waste characteristics, etc.);

(b) Stored radioactive waste (including identification, origin, location, physical and chemical characteristics);

(c) Material from which Regulatory control has been removed or that has been discharged to the environment (including data related to the process);

(d) Disused sealed radioactive sources returned to suppliers;

(e) Radioactive waste and disused sealed radioactive sources transferred to management waste facility or another user; and

(f) Non compliances and action taken in response.

7.14. In case of processing and storage facilities for radioactive waste the records concerning waste management activities should include:

(a) The data of waste and disused sealed radioactive sources collected or received from generating facilities;

(b) The data needed for a national inventory of waste;

(c) The data needed for waste characterization;

(d) The records from the control processes for pretreatment, treatment, packaging and conditioning;

(e) The documents on the procurement of containers required to provide confinement for a certain period (e.g. in a disposal facility);

(f) The specifications for waste packages and audit records for individual containers and packages;

(g) Trends in operating performance;

(h) Non-compliances with the specifications for waste packages and the actions taken to rectify them; and

(i) The data of the materials that were cleared or discharged.

(j) lessons learned from events and incidents

7.15. The operators should provide means and ensure, where necessary, that site plans, engineering drawings, specifications and process descriptions as well as operating procedures and safety related operating instructions are maintained. The results from quality control activities as well as operating activities should also be well documented and recorded.

7.16. The operator should also keep records of information relating to the safety of the predisposal radioactive predisposal management facility during commissioning, operation, modification or decommissioning.

7.17. The regulatory body should define the timing, scope and content of periodic reports to be submitted by the operator and reports describing any non-compliance with safety requirements or unplanned situations. Reports may include the following:

(a) details of materials from which regulatory control has been removed (clearance) or which have been discharged to the environment;

(b) details of disused sealed radioactive radiation sources returned to suppliers;

(c) the current inventory of radioactive waste including: identification, origin, location, physical and chemical characteristics, radionuclide composition, total activity or activity concentration (with the measurement or estimation date) and, as appropriate, a record of radioactive waste removed from the facility;

(d) safety assessment methods used;

(e) results of safety assessments;

(f) effluent and environmental monitoring results;

(g) results of internal audits and other findings by the person responsible for the safety of radioactive waste management; and

(h) emergency situations, if any, occurred during processing of the waste, methods adopted for its handling and lessons learned.

7.18. If any radioactive waste has been lost, stolen or is missing or effluent has been discharged above the established limits, the user and operator should promptly inform the regulatory body and submit a written report on the matter and actions taken.

7.19. When waste is being transferred, associated records need to be available to the operator of the subsequent step.

7.20. The regulatory body may also require the user or operator to submit on a regular basis a summary of the status of the waste generation and management.

SAFETY CULTURE

7.21. Efforts should be directed to ensuring that an appropriate safety culture exists in all the organizations involved with the generation and management of radioactive waste and its regulatory control. This should be aimed at creating a necessary awareness of the need for proper management of radioactive waste at all levels within the various organizations and should discourage complacency in any aspect of related operations [2, 4].

7.22. All parties concerned should continue to question the adequacy and effectiveness of radioactive waste management programmes and seek at all times to make improvements in the arrangements concerning safety.

Appendix I

TYPICAL RADIATION SOURCES USED IN MEDICINE, INDUSTRY AND RESEARCH AND THE ASSOCIATED RADIOACTIVE WASTE GENERATED

I.1. Sources of ionizing radiation are produced for a broad range of applications in medicine, industry, research and other areas. As a result of the initial production of the radioactive materials and their diversified use, radioactive waste in various forms is generated. In general, this waste is comprised of radioactive materials which are no longer useful and are therefore regarded as waste, items which have become contaminated, such as paper, plastic gloves and covers, counting tubes, glassware, washing liquids and excreta from patients to whom radionuclides have been administered. In addition to such routine waste, waste of variable composition may also arise from incidents or accidents involving radioactive materials. The risks associated with the waste and thus the precautions that should be taken vary widely depending on the application, the radionuclides, and the quantities.

I.2. Radioactive materials are used in two different forms. Sealed radioactive sources are used in a form where the probability of dispersion of the radioactive contents is very low. Unsealed sources are dispersible although combined with the chemical medium of which they are a part. Tables I.1 and I.2 provide information on the main unsealed and sealed radioactive sources used in medicine, industry and research.

RADIONUCLIDE PRODUCTION

I.3. Particle accelerators and nuclear reactors are used in radionuclide production, which results in waste generation. The radionuclides generated in particle accelerators and reactors are produced in targets and capsules which are removed from the facilities for processing and purification. Small volumes of liquid waste with relatively high activities and larger volumes of dry, low level solid waste are generated.

MEDICAL APPLICATIONS

I.4. Radioactive materials are used in medicine for diagnosis, therapy and research including:

(a) in vitro radioassay for clinical diagnosis and research using unsealed radionuclides;

(b) in vivo use of radiopharmaceuticals for clinical diagnosis, therapy and medical research using unsealed radionuclides; and

(c) radiotherapy using sealed sources which are either implanted inside the patient or used in an external device.

I.5. Commercially available kits containing only kilobecquerel quantities of radionuclides are used for in vitro radioassay. In many countries, this activity is not controlled by the regulatory body because the used kits are eligible for exemption. I-125 is the main radionuclide, with each assay usually involving a very small amount of activity. Following each individual assay and after the expiry date of the kit, the radioactive material and contaminated items are normally considered as normal waste.

I.6. For the main in vivo applications, the particular organ to be studied or treated governs the type of radiopharmaceutical used and the quantity administered to the patient. Of the radionuclides in use for imaging work, Tc-99m is the most common, having a radioactive half-life of 6 hours. It is normally eluted in a sterile environment from a commercially supplied generator containing a core of Mo-99. Since the half-life of the latter radionuclide is 66 hours, generators need to be replaced at approximately weekly intervals. The waste arising from preparation of Tc-99m labelled agents, such as discarded vials, syringes and swabs are potentially contaminated with the radionuclide, but the radioactivity decays away rapidly due to the short half-life, so that the regulatory control can be removed and the waste disposed of as non-radioactive. However, when applying decay storage for high amounts of Tc-99m it should be noticed that the decay product of Tc-99m, Tc-99, is radioactive and has a very long half-life.

I.7. Radionuclides such as I-131, P-32, Y-90, Ir-192 and Sr-89 are administered to patients in activities ranging from 200 MBq to 11 GBq for therapeutic purposes. In therapeutic applications, due attention should be paid to the radioactive contaminants contained in waste from patients, such as excreta and soiled linen.

I.8. Sealed radioactive sources containing some other radionuclides such as Co-60, Ir-192 and Cs-137 are used for patient therapy; as temporary implants, for external beam therapy and for radiation of blood products.

TABLE I.1. TYPICAL UNSEALED RADIOACTIVE SOURCES USED IN MEDICINE AND BIOLOGICAL RESEARCH

Radionuclide	Half-life	Principal application	Typical quantity per application	Waste characteristics
^{3}H	12.3 a	Radiolabelling Biological research Organic synthesis	Up to 50 GBq	Solvents, solid, liquid
^{11}C	20.3 min	Positron emission Tomography Lung ventilation studies	Up to 2 GBq	Solid, liquid
^{14}C	5730 a	Medical diagnosis Biological research Labelling	Less than 1 MBq Up to 50 GBq Up to 50 GBq	(Exhaled CO_2) Solid, liquid Solvent
^{15}O	122 s	Positron emission tomography Lung ventilation studies	Up to 2 GBq	Solid, liquid
^{18}F	1.8 h	Positron emission Tomography	Up to 500 MBq	Solid, liquid
^{24}Na	15.0 h	Biological research	Up to 5 GBq	Liquid
^{32}P ^{33}P	14.3 d 25.4 d	Therapeutic nuclear medicine Biological research	Up to 200 MBq Up to 50 MBq	Solid, liquid
^{35}S	87.4 d	Medical and biological research	Up to 5 GBq	Solid, liquid
^{36}Cl	3.01×10^{5} a	Biological research	Up to 5 MBq	Gaseous, solid, liquid
^{45}Ca	163 d	Biological research	Up to 100 MBq	Mainly solid, some liquid
^{46}Sc	83.8 d	Medical and biological research	Up to 500 MBq	Solid, liquid
^{51}Cr	27.7 d	Diagnostic nuclear medicine Biological research	Up to 5 MBq Up to 100 MBq	Solid Mainly liquid effluent
^{57}Co ^{58}Co	271.7 d 70.8 d	Diagnostic nuclear medicine Biological research	Up to 50 MBq --	Solid, liquid effluent
^{59}Fe	44.5 d	Diagnostic nuclear medicine Biological research	Up to 50 MBq	Solid, mainly liquid
^{67}Ga	3.3 d	Diagnostic nuclear medicine	Up to 200 MBq	Solid, liquid
^{68}Ga	68.2 min	Positron emission Tomography	Up to 2 GBq	Solid, liquid
^{75}Se	120 d	Diagnostic nuclear medicine	Up to 10 MBq	Solid, liquid
^{81m}Kr	13.3 s	Lung ventilation studies	Up to 6 GBq	Gaseous
^{85}Sr	64.8 d	Biological research	Up to 50 MBq	Solid, liquid
^{86}Rb	18.7 d	Medical and biological research	Up to 50 MBq	Solid, liquid
^{82m}Rb	6.2 h	Diagnostic nuclear medicine	Up to 50 MBq	Solid, liquid
^{89}Sr	50.5 d	Therapeutic nuclear medicine	Up to 300 MBq	Solid, liquid
^{90}Y	2.7 d	Diagnostic nuclear medicine Medical and biological	Up to 300 MBq	Solid, liquid

Radionuclide	Half-life	Principal application	Typical quantity per application	Waste characteristics
		research		
^{95}Nb	35.0 d	Medical and biological research	Up to 50 MBq	Solid, liquid
^{99m}Tc	6.0 h	Diagnostic nuclear medicine Biological research Nuclide generators	Up to 100 GBq	Solid, liquid
^{111}In	2.8 d	Clinical measurements Biological research	Up to 50 MBq	Solid, liquid
^{123}I ^{125}I ^{131}I	13.2 h 60.1 d 8.0 d	Medical and biological research Diagnostic nuclear medicine Therapeutic nuclear medicine	Up to 500 MBq Up to 11 GBq	Solid, liquid, occasionally vapour
^{113}Sn	155.0 d	Medical and biological research	Up to 50 GBq	Solid, liquid
^{133}Xe	5.3 d	Diagnostic nuclear medicine	Up to 400 MBq	Gaseous, solid
^{153}Sm	1.9 d	Therapeutic nuclear medicine	Up to 8 GBq	Solid, liquid
^{169}Er	9.3 d	Therapeutic nuclear medicine Diagnostic nuclear medicine	Up to 500 MBq	Solid, liquid
^{198}Au	2.7 d	Therapeutic nuclear medicine Diagnostic nuclear medicine	Up to 500 MB	Solid, liquid
^{201}Tl	3.0 d	Diagnostic nuclear medicine	Up to 200 MBq	Solid, liquid
^{203}Hg	46.6 d	Biological research	Up to 5 MBq	Solid, liquid

TABLE I.2. SEALED RADIOACTIVE SOURCES USED IN MEDICINE, INDUSTRY AND RESEARCH

Radionuclide	Half-life	Application	Source activity	Comments
^{241}Am ^{153}Gd ^{125}I ^{239}Pu–Be	433.0 a 244.0 d 60.1 d 2.41×10^{4} a	Bone densitometry	1–10 GBq 1–40 GBq 1–10 GBq	Mobile units
^{198}Au ^{137}Cs ^{226}Ra ^{32}P ^{60}Co ^{90}Sr ^{103}Pd ^{125}I ^{192}Ir ^{106}Ru	2.7 d 30.0 a 1600 a 14.3 d 5.3 a 29.1 a 17.0 a 60.1 d 74.0 d 1.01 a	Manual brachytherapy	50–500 MBq 30–300 MBq 50–500 MBq 50–1500 MBq 50–1500 MBq 50–1500 MBq 200–1500 MBq	Small portable sources
^{137}Cs ^{192}Ir	30.0 a 74.0 d	Remote after-loading brachytherapy	0.03–10 MBq 200 TBq	Mobile units
^{60}Co ^{137}Cs 226Ra	5.3 a 30.0 a 1600 a	Teletherapy	50–1000 TBq 500 TBq	Fixed installations
^{60}Co ^{137}Cs	5.3 a 30.0 a	Whole blood irradiation	50–1000 TBq 2–100 TBq	Fixed installations
^{60}Co ^{137}Cs	5.3 a 30.0 a	Research	Up to 750 TBq Up to 13 TBq	Fixed installations
60Co	5.3 a	Sterilization	Up to 40 PBq	Fixed installations
^{63}Ni ^{137}Cs ^{57}Co ^{226}Ra ^{147}Pm ^{36}Cl ^{129}I	100 a 30.0 a 271.7 d 1600 a 2.62 a 3.01×10^{5} a 1.57×10^{7} a	Calibration sources, anatomical markers, sources as standards in instruments	<4 MBq <4 MBq Up to 400 MBq <10 MBq <4 MBq <4 MBq <4 MBq	Fixed installations in instruments or mobile sources
^{22}Na ^{55}Fe ^{85}Kr ^{90}Sr 109 Cd ^{134}Cs ^{137}Cs ^{147}Pm ^{241}Am–Be ^{238}Pu ^{252}Cf	2.6 a 2.6 a 10.7 a 28.1 a 1.27 a 2.1 a 30.0 a 2.62 a 433 a 87.7 a 2.6 a	Thickness gauges, density gauges, well logging, moisture detectors, X ray fluorescence	 Up to 5 GBq Up to 100 GBq Up to 10 GBq Up to 20 GBq Up to 10 GBq Up to 2 GBq Up to 500 GBq Up to 5 GBq Up to 10 GBq	Mobile equipment Fixed in equipment
^{210}Po	138 d	Static eliminators	Up to 20 GBq	Mobile equipment
^{3}H ^{63}Ni	12.3 a 100 a	Electron capture detectors	Up to 10 TBq Up to 50 GBq	Mobile equipment
^{169}Yb ^{160} Tm 60 Co 75 Se 137Cs 192 Ir	32 d 128.6 d 5.3 a 120 d 30.0 a 74.0 d	Industrial radiography	Up to 1 TBq Up to 1 TBq Up to 15 TBq Up to 2 TBq Up to ??? Up to 5 TBq	Mobile equipment

Research applications

I.9. Research using radionuclides may involve the following:

(a) Production and labelling of compounds resulting in waste containing megabecquerel activities of radionuclides, such as H-3, I-125, C-14 or P-32. The range of radionuclides is normally fairly restricted and the activity content of the labelled compounds is low.

(b) Study of metabolic, toxicological or environmental pathways associated with a large range of compounds such as drugs, pesticides, fertilizers and minerals. Work may be related to areas such as new drug manufacture, crop production and environmental studies. Animals may also be involved, resulting in radioactive excreta, carcasses and bedding. The radionuclides most commonly employed in studying the toxicology of many chemical compounds and their associated metabolic pathways are C-14 and tritium, as they can be readily incorporated into complex molecules, while P-33 is quite widely used as tracer in genetics.

(c) Development of clinical processes and applications of prepared compounds (such as pharmaceuticals) for work involving humans as well as animals.

(d) Research in the nuclear fuel cycle field which is not carried out at a nuclear fuel cycle facility. The research is usually conducted in laboratories, using a small amount of fissile material (uranium, plutonium) and relatively long lived fission products, mainly Cs-137 and Sr-90. Waste generated includes solid materials and liquids containing fission products and fissile material.

(d) Basic research in the fields of physics, materials and biology (e.g.; use of Co-57 in Mossbauer Spectroscopy and use of H-3 as a tracer in hydrology).

Industrial and other applications

I.10. Sealed radioactive sources are used extensively for various industrial applications. Such applications include non-destructive testing (radiography and gauging) and sterilization of food and other products. Sealed radioactive sources are also used for process control and for calibration of laboratory equipment. The dominant radionuclide is present in a very concentrated form with the total activity depending on the application and the nature of the emission from the sources. Sealed radioactive sources are considered to be waste by users when they have decayed to the extent that they are no longer useful for their original purpose, or because the appliance in which they are housed has become outdated, or because routine tests have indicated the source to be leaking.

I.11. An example of the industrial use of unsealed radioactive sources as a tracer is the evaluation of wear and corrosion of key components in plant and machinery, such as the wear of engine components, furnace linings and metallic surfaces. Other applications involving unsealed sources include monitoring of sewage treatment works and studying the performance of landfill disposal sites, the movement of groundwater, and the dispersion and dilution of cooling water or gaseous effluents. In most cases short lived radioactive tracers are used. The industrial applications of radioisotope tracer techniques are often of greater magnitude than those on a laboratory scale. Waste can be generated from radionuclides used in certain industrial products such as smoke detectors (Am-241), exit signs (H-3), and static eliminators (Po-210). Attention should be paid for waste generated from these sources particularly in large quantities.

I.12. Both sealed and unsealed radioactive sources are also used for teaching students, emergency planners and civil defines members. All these applications generate waste with activities that are normally very low.

WASTE TYPES

I.13. According to its physical properties radioactive waste can be liquid, solid or gaseous. Liquid waste may be further subdivided into aqueous and organic, solid waste into compressible and/or non-compressible and combustible and/or non-combustible.

Aqueous radioactive waste

I.14. At radioisotope production facilities, aqueous waste results from chemical processing, mainly the etching and dissolving of target materials. The waste which is of small volume is normally contaminated with of radionuclide impurities. Depending upon the chemical processes used, the aqueous waste may be chemically very active.

I.15. In hospitals, the aqueous waste types depend on the kind of therapeutic and diagnostic nuclear medicine techniques being carried out. Most of the radionuclides used for diagnosis are very short lived (half-life less than 10 days).

I.16. Studies of metabolic pathways may involve laboratory animals. The animals may be involved at various stages of the work, resulting in radioactive excreta, blood, carcasses and bedding. Some of this material may become part of the aqueous waste stream creating a potential biological hazard. In some cases longer lived radionuclides are used to label microspheres for such studies. While these microspheres are theoretically solid, they may easily become suspended in the liquid waste. Small animal carcasses may also be macerated to a liquid form to make them suitable for discharge as aqueous based waste.

I.17. Aqueous waste also arises from radiochemical neutron activation analysis. This waste can be extremely variable in chemical composition but the radionuclides are often relatively short lived. In small nuclear research centres, liquid waste may be contaminated with both short lived radionuclides and longer lived radionuclides such as C-14 and tritium. The volume of liquid waste produced by individual users of radioactive materials is not likely to be large. However, the waste from radiolabelling processes may have a relatively high activity concentration and should generally be kept separate from lower activity wash solutions. It is unlikely that alpha emitting radionuclides (other than uranium and thorium compounds) or relatively long lived gamma emitters such as Cs-137 and Co-60 will be used.

I.18. Whatever the field of work, contaminated equipment and facilities may need to be cleaned, decontaminated and/or disinfected, resulting in radioactive aqueous waste which may have associated biological hazards. This waste may contain large quantities of complexing agents used to solubilize the radioactive contaminant.

Liquid organic radioactive waste

I.19. Liquid organic radioactive waste typically includes vacuum pump oil, lubricating oil and hydraulic fluids, scintillation solutions from analytical laboratories, solvents from research on solvent extraction and uranium refining, and miscellaneous organic solvents. Most waste of these types arises from work in nuclear research centres. Depending on the origin, the waste contains relatively small quantities of beta and gamma emitting radionuclides. The volume of liquid organic waste produced from nuclear applications of radionuclides is generally small compared with amounts of radioactive waste of other classes.

I.20. Organic scintillation liquids normally result from measurements of low energy beta and gamma emitters in samples consisting of aromatic organic compounds, and the sample under investigation. The most common radionuclides contained in the waste are tritium and C-14, with I-125 and S-35 less common.

I.21. A number of non-water-miscible organic solvents may arise in a variety of operations. These include carbon tetrachloride, trichloroethane and perchloroethylene. Where small quantities of water miscible organic solvents are used (acetone, alcohol) their treatment is normally as if they were aqueous waste.

I.22. In nuclear research centres, the solvent most commonly used for extraction of uranium and plutonium is tributyl phosphate (TBP). For the extraction process TBP is diluted, usually with a liquid such as paraffin. Sometimes other organic compounds are used for the extraction of heavy metals, including tri- and tertiary amino-compounds, though the volumes are usually very small in comparison to TBP.

Solid radioactive waste

I.23. Most solid waste produced in medical and research laboratories falls into the category of combustible waste. This group includes tissues, swabs, paper, cardboard, plastics, rubber gloves, protective clothing and masks, animal carcasses and biological material.

I.24. Non-combustible waste includes glassware, scrap metal, and waste from the decommissioning of facilities that used radionuclides.

I.25. It should be noted that these categories are not mutually exclusive. This classification, which should be employed for solid waste segregation, is based on the degree of volume reduction which may reasonably be expected by compaction or incineration. The waste generated by medical, industrial, research and teaching activities is predominantly of a combustible nature and may also be categorized as compressible, provided that there is no biological hazard.

I.26. The trash component of solid waste includes protective clothing, plastic sheeting and bags, rubber gloves and mats, shoe covers, wipe rags and towels. Much of this material is only marginally contaminated. The material possibly exhibits no measurable contamination but is initially classified as radioactive waste purely because it arose in controlled areas. From those materials it may be possible to remove regulatory control and they may be disposed of as industrial waste [5]. However, certain individual trash items may be significantly contaminated, particularly if they have been directly involved in procedures or experiments involving unsealed radioactive sources of high activity.

I.27. Disused sealed radioactive sources may have a widely varying activity depending on their original use: this varies from a few kilobecquerels for check sources up to many terabecquerels for teletherapy sources. While disused sealed radioactive sources are usually a small fraction of the volume of radioactive waste generated by a particular operator, they may dominate the activity content of the waste arisings. It should be noted that, although the radiation output of teletherapy sources and other large sources may have fallen below useful levels, the potential for injury from such sources remains substantial. Particular note is made of the fact that teletherapy caesium-137 sources normally contain caesium compounds in dispersible form and represent a severe hazard should their primary containment be breached [17].

I.28. Contaminated material and equipment may be generated either from medical or research activities and may constitute components of dismantled experimental rigs, or surgical implants. They may be made of glass, metal or plastic, and their activity varies widely according to use (see Tables I and II).

I.29. Activated materials may include shielding materials and isotope cans from isotope production or materials testing in research reactors. Their activities may be expected to be dominated by that of Co-60 and other activated impurities in steel. For cyclotron based production the dominating nuclide would be Zn-65, produced from copper. Activity is a function of both irradiation and period of decay. Such items are unlikely to be either combustible or compressible.

I.30. Animal carcasses have activity concentrations varying with animal species and experimental procedures. Carcasses may present biological and chemical hazards if they are permitted to decompose to any significant extent prior to disposal. Carcasses contaminated with long lived radionuclides necessitate particularly careful consideration, especially when incineration is not an available disposal option.

I.31. Decommissioning of predisposal waste management facilities may result in solid waste comprising construction materials, equipment components and soil. The main features typifying decommissioning waste are the relatively large size of the waste items and the presence of long lived radionuclides.

Gaseous or airborne waste

I.32. Gaseous or airborne radioactive waste may be generated from a range of nuclear applications. A specific medical application involves the use of radioactive gases such as Xe-133 or Kr-81m or technetium-99m and short lived positron emitters like F-18 and C-11 for the investigation of the ventilation of the lungs.

Appendix II

FAULT SCHEDULE FOR SAFETY AND ENVIRONMENTAL IMPACT ASSESSMENT

TABLE II.1. FAULT SCHEDULE SETTING OUT A SIMPLIFIED APPROACH TO SAFETY ASSESSMENT

Process stages	Hazard	Control measures		Mitigated risk	Contingency arrangements
		Engineered	Administrative		
Identify all stages and interfaces in the waste management deliberation and decision-making process as related to safety, security, and potential environmental impacts	Identify hazards for each stage of decision-making for normal and abnormal conditions including external events (e.g.; flood, fire, earthquakes, tsunamis, etc.)	Provide information on engineered control measures. Examples include, but are not limited to: protection devices, containment, shielding, thermal and/or electrical insulation, security devices and/or systems	Provide information on administrative control measures. Examples include, but are not limited to: operating instructions, procedures, limits, conditions, requirements	Quantify mitigate (controlled) risk for each stage under normal and abnormal conditions once control measures have been taken into account	Provide information on contingency measures. Examples include, but are not limited to: Radiological and personal protective equipment, power shut off devices, external but supporting safety arrangements

Appendix III

MANAGEMENT FLOW DIAGRAM FOR SOLID RADIOACTIVE WASTE

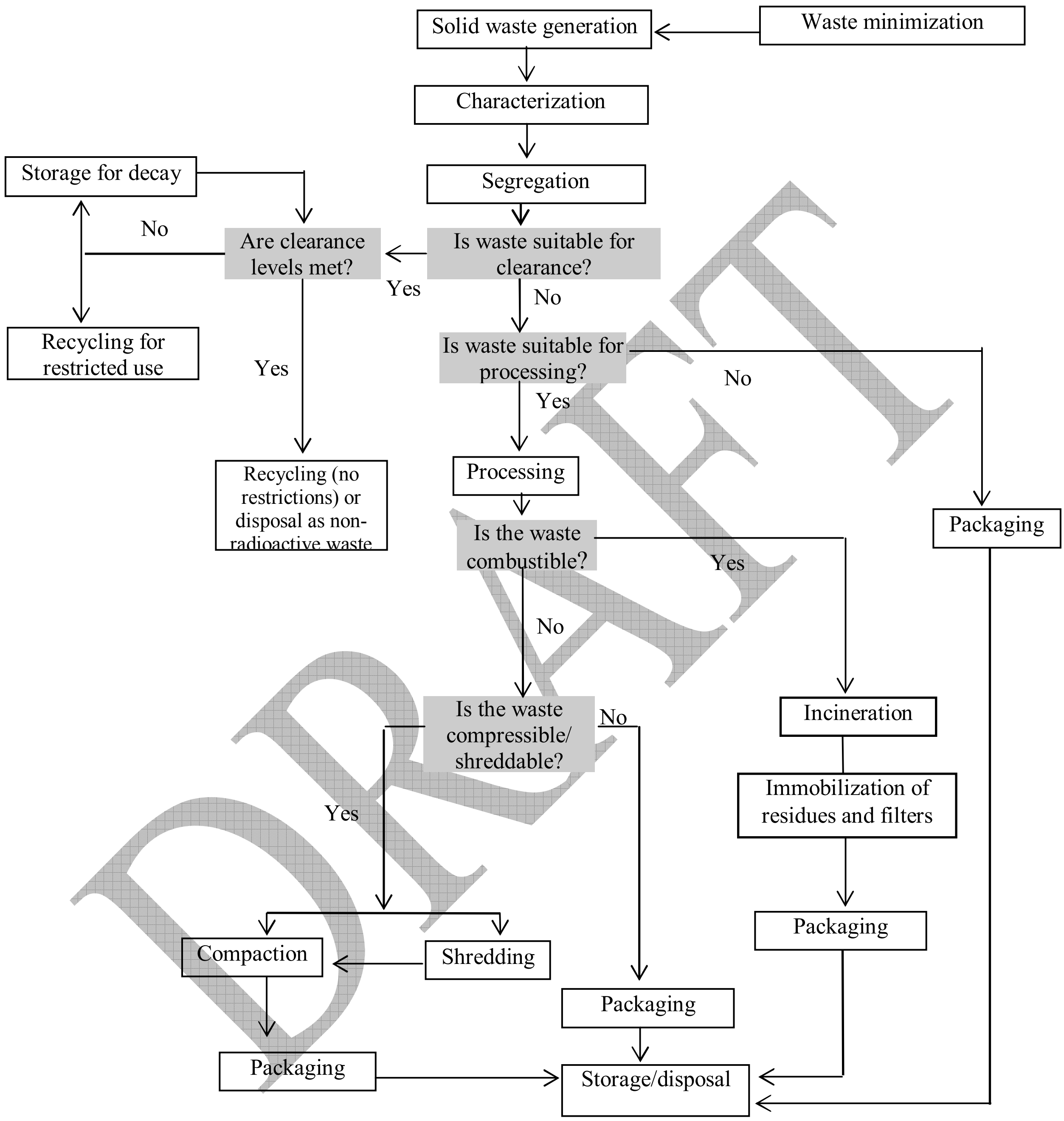

FIG. III.1. Flow diagram illustrating the steps in the management of solid radioactive waste

Appendix IV

MANAGEMENT FLOW DIAGRAM FOR BIOLOGICAL RADIOACTIVE WASTE

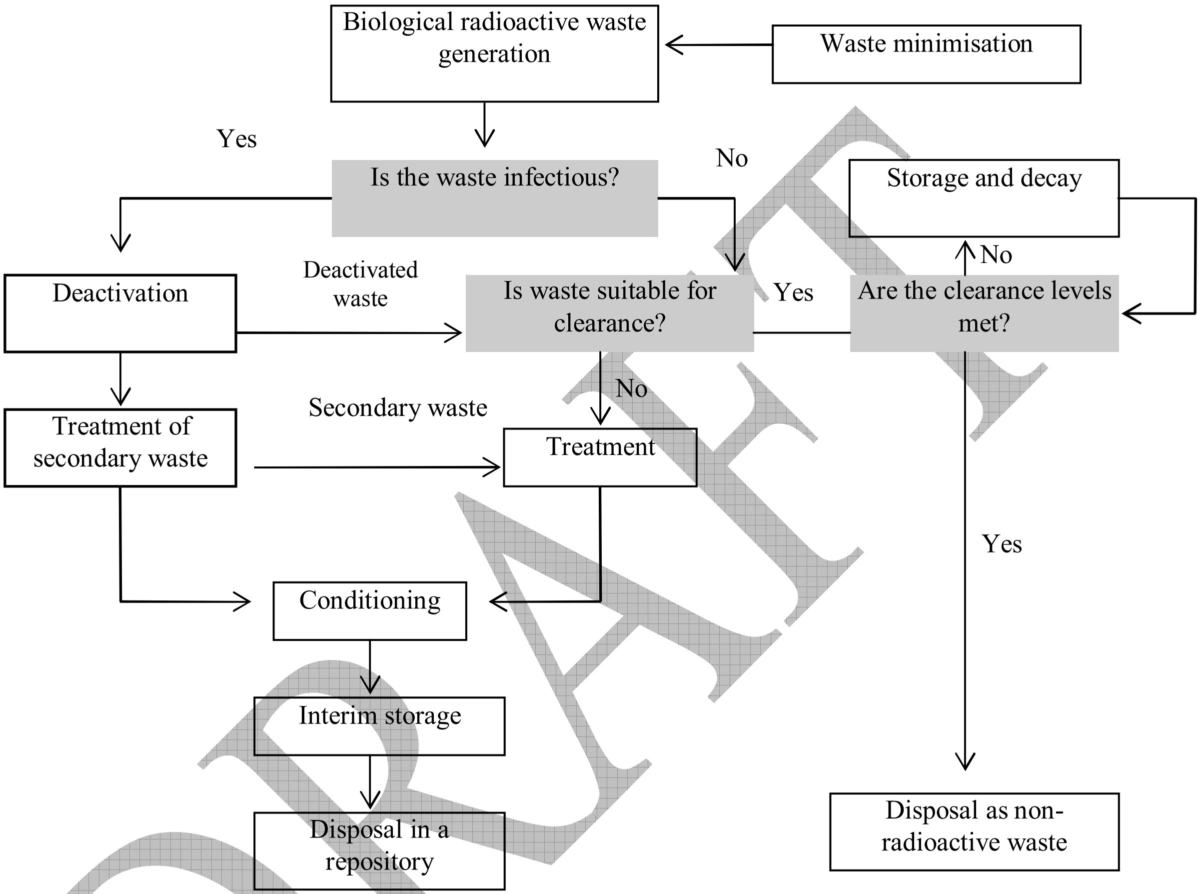

Fig. IV.1. Flow diagram illustrating the main steps in the management of biological radioactive waste

Appendix V

MANAGEMENT FLOW DIAGRAM FOR DISUSED SEALED SOURCES

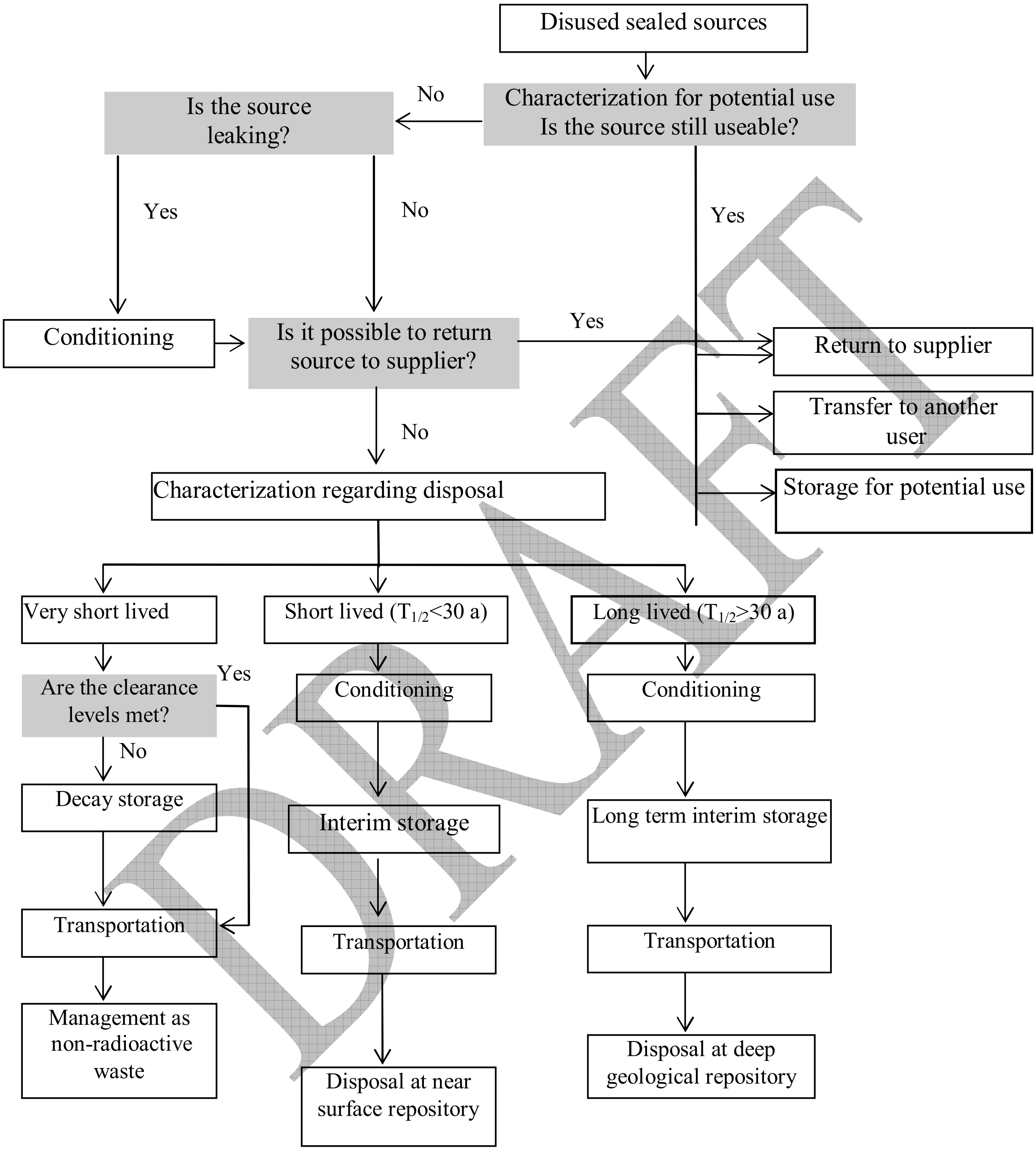

Fig. V.1. Flow diagram illustrating the main steps in the management of disused sealed sources

Annex I

EXAMPLES OF DISUSED SEALED RADIOACTIVE SOURCES AND IDENTIFICATION OF TECHNIQUES FOR THEIR MANAGEMENT

TABLE VI.I. EXAMPLES OF COMMON DISUSED SEALED SOURCES AND THE TECHNIQUES AND EQUIPMENT USED FOR THEIR SAFE MANAGEMENT

Categories						Handling equipment		Monitoring	Packaging	Storage container
Sources	Isotope	Half-life	Applications							
□	Low activity									
	^{241}Am	432.2 a	Smoke detectors	Lightning rods	Static eliminators	Gloves box	Latex gloves	□□□Detection	Stainless steel internal drum	Drum with concrete
	^{210}Po	138.38 d	Static eliminators				Latex gloves			
	^{238}Pu	87.74 a	X ray fluorescence Analy:			Gloves box		□□□Detection	Tight container	Drum with concrete
	^{239}Pu	24181 a	Smoke detectors			Gloves box			Tight container	
□□□□	Low activity		Long or short half-life							
	^{241}Am	432.2 a	Gauges	X ray fluorescence analyser	Bone densitometry		Tongs		Stainless steel	Drum with concrete
	^{90}Sr/^{90}Y	28.2 a	Gauges	Brachytherapy			Rubber gloves		internal drum	
	^{147}Pm	2.6 a	Gauges				Rubber gloves			
	^{63}Ni	100 a	Electron capture detectors				Rubber gloves			
	^{109}Cd	462.6 d	X ray fluorescence Analy:				Rubber gloves			
	^{60}Co	5.3 a	Gauges	Calibration		Shielded screen	Tongs	□□□□Detection	Lead shielded pot	Drum concrete + Pb
	^{137}Cs	30.2 a	Gauges	Calibration		Shielded screen	Tongs		Lead shielded pot	Drum concrete + Pb
□□□	High activity		Short half-life							
	^{192}Ir	73.8 d	Gammagraphy			Lead hot cell	manipulators	□□□□Detection	Lead shielded pot	Drum with concrete
	^{170}Tm	134 d	Gammagraphy			Shielded screen	Tongs		Stainless steel basket	
	^{169}Yb	32 d	Gammagraphy			Shielded screen	Tongs			
	^{75}Se	120 d	Gammagraphy			Shielded screen	Tongs			
□□□	High activity		Long half-life							
	^{60}Co	5.3 a	Gammagraphy			Lead hot cell	manipulators	□□□□Detection	Lead container	400 L Drum with concrete
	^{60}Co	5.3 a	Teletherapy			Concrete hot cell	manipulators		Lead container	or concrete container
	^{60}Co	5.3 a	Irradiators			Concrete hot cell	manipulators		Specific to be defined	Specific to be defined
	^{137}Cs	30.2 a	Irradiators			Concrete hot cell	manipulators		Specific to be defined	Specific to be defined
Special										
	^{226}Ra	1600 a	Lightning rods	Static eliminators		Gloves box	Tongs	□□Detection	Tight container	Lead shielded container
	^{85}Kr	10.7 a	Gauges	Lightning rods		Gloves box	Tongs	Air control		
	^{3}H	12.3 a	Electron capture detectors	X ray fluorescence. Analyser		Gloves box	Tongs	^{3}H Control	Stainless steal	Drum with concrete
Neutron										
Neutron	^{241}Am/Be	432.2 a	Moisture detectors	Oil well logging		Neutron	protection	Neutron detector		Neutron protection
Neutron	^{252}Cf	2.65 a	Moisture detectors	Oil well logging	Brachytherapy	Neutron	protection			
Neutron	^{226}Ra/Be	1600 a	Moisture detectors	Oil well logging		Neutron	protection			
Neutron	^{238}Pu/Be	87.74 a	Moisture detectors	Calibration instrument		Neutron	protection			

Annex II

EXAMPLE OF A STRATEGY ON IDENTIFICATION AND LOCATION OF DISUSED SEALED RADIOACTIVE SOURCES

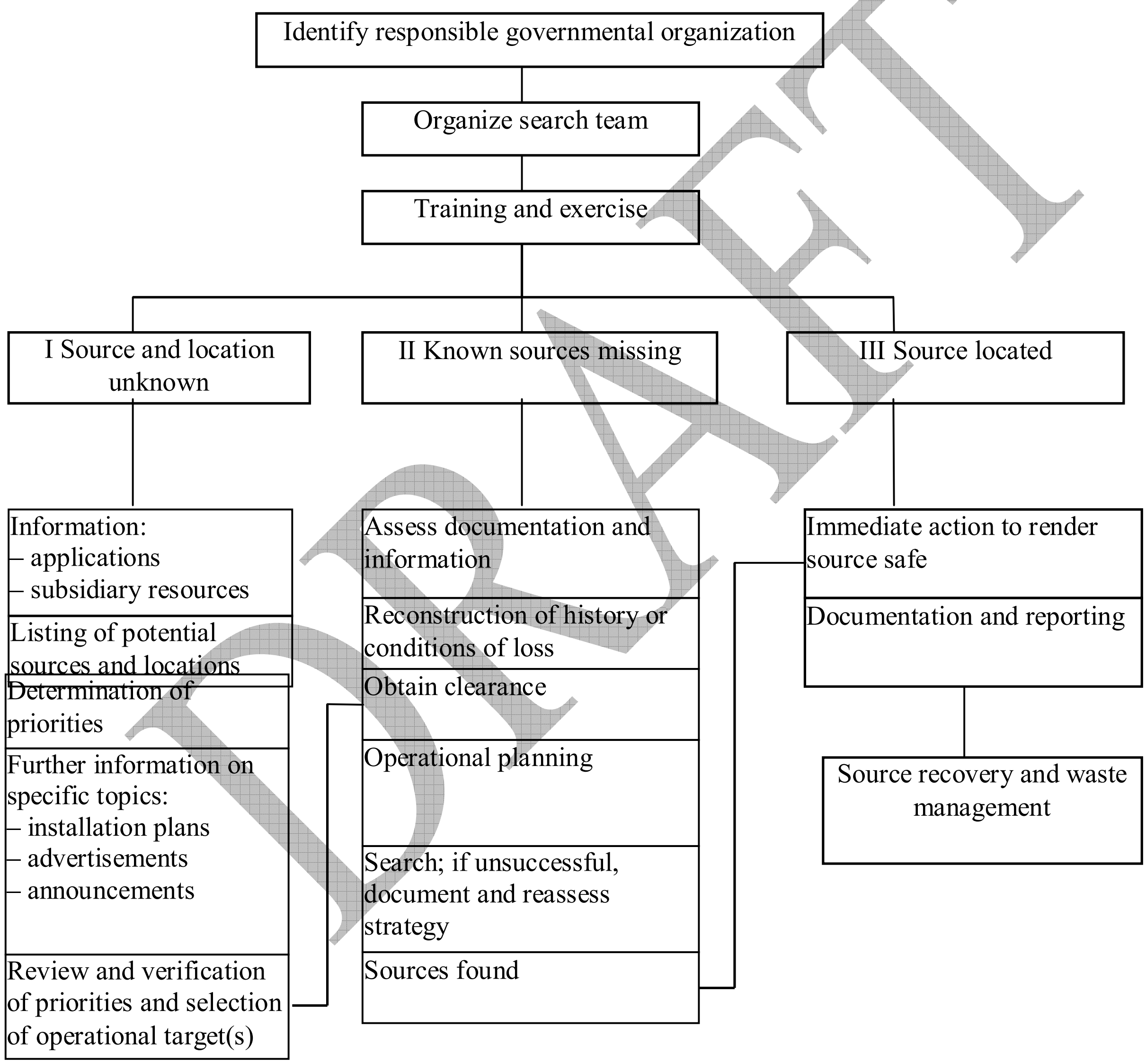

Fig. VII.1. An example strategy for identification and location of spent and/or disused sealed radioactive sources

REFERENCES

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

[2] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste, IAEA Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009).

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

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Low and Intermediate Level Radioactive Waste, IAEA Safety Standards Series No. WS-G-2.5, IAEA, Vienna (2003).

[6] 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).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Disposal of Radioactive Waste, IAEA Safety Standards Series No. SSR-5, IAEA, Vienna (2011).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Management of Radioactive Waste from the Mining and Milling of Ores, IAEA Safety Standards Series No. WS-G-1.2, IAEA, Vienna (2002).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Storage of Radioactive Waste, IAEA Safety Standards Series No. WS-G-6.1, IAEA, Vienna (2006).

[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2012 Edition, IAEA Safety Standards Series No. SS-R-6, IAEA, Vienna (2012).

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, 2012 Edition, IAEA Safety Standards Series No. SSG-26, IAEA, Vienna (2014).

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Concepts of Exclusion, Exemption and Clearance, IAEA Safety Standards Series No. RS-G-1.7, IAEA, Vienna (2004).

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014).

[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Medical, Industrial and Research Facilities, IAEA Safety Standards Series No. WS-G-2.2, IAEA, Vienna (1999).

[15] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Case and Safety Assessment for Predisposal Management of Radioactive Waste, IAEA Safety Standards Series No. GSG-3, IAEA, Vienna (2013).

[16] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 1990 Recommendations of the ICRP, ICRP Publication 103, Pergamon Press, Oxford and New York (2007).

[17] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection Policy for the Disposal of Radioactive Waste, ICRP Publication 77, Pergamon Press, Oxford and New York (1997).

[18] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiation Protection Recommendations as Applied to the Disposal of Long-lived Solid Radioactive Waste, ICRP Publication 81, Pergamon Press, Oxford and New York (2000).

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

[20] 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 OFFICE FOR THE CO-ORDINATION OF

HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GS-R-2, IAEA, Vienna (2002).

[21] INTERNATIONAL ATOMIC ENERGY AGENCY, Occupational Radiation Protection, IAEA Safety Standards Series No. RS-G-1.1, IAEA, Vienna (1999).

[22] INTERNATIONAL ATOMIC ENERGY AGENCY, Assessment of Occupational Exposure Due to Intakes of Radionuclides, IAEA Safety Standards Series No. RS-G-1.2, IAEA, Vienna (1999).

[23] INTERNATIONAL ATOMIC ENERGY AGENCY, Assessment of Occupational Exposure Due to External Sources of Radiation, IAEA Safety Standards Series No. RS-G-1.3, IAEA, Vienna (1999).

[24] INTERNATIONAL ATOMIC ENERGY AGENCY, Environmental and Source Monitoring for Purposes of Radiation Protection, IAEA Safety Standards Series No. RS-G-1.8, IAEA, Vienna (2005).

[25] INTERNATIONAL ATOMIC ENERGY AGENCY, Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, IAEA International Law Series No. 1, IAEA, Vienna (2006).

[26] INTERNATIONAL ATOMIC ENERGY AGENCY, Classification of Radioactive Waste, IAEA Safety Standards Series No. GSG-1, IAEA, Vienna (2009).

[27] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-R-3, IAEA, Vienna (2006).

[28] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-G-3.1, IAEA, Vienna (2006).

[29] INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC 225/Revision 5), IAEA Nuclear Security Series No. 13, IAEA, Vienna (2011).

[30] The Agency's Safeguards System, INFCIRC/66/Rev.2, IAEA, Vienna (1968).

[31] Model Protocol Additional to the Agreement(s) Between State(s) and the International Atomic Energy Agency for the Application of Safeguards, INFCIRC/540(Corrected), IAEA, Vienna (1997).

[32] The Structure and Content of Agreements between the Agency and States Required in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons, INFCIRC/153(Corrected), IAEA, Vienna (1972).

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

[34] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for the Processing, Handling and Storage of Radioactive Waste, IAEA Safety Standards Series No. GS-G-3.3, IAEA, Vienna (2008).

[35] INTERNATIONAL ATOMIC ENERGY AGENCY, Strategy and Methodology for Radioactive Waste Characterization, IAEA-TECDOC-1537, IAEA, Vienna (2007).

[36] INTERNATIONAL ATOMIC ENERGY AGENCY, National Strategy for Regaining Control over Orphan Sources and Improving Control over Vulnerable Sources, IAEA Safety Standards Series No. SS-G-19, IAEA, Vienna (2011).

[37] INTERNATIONAL ATOMIC ENERGY AGENCY Release of Sites from Regulatory Control on Termination of Practices, IAEA Safety Standards Series No. WS-G-5.1, IAEA, Vienna (2006).

CONTRIBUTORS TO DRAFTING AND REVIEW