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Licence Applications for Low and Intermediate Level Waste Predisposal Facilities: A Manual for Operators

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FOREWORD

Radioactive waste is generated from the production of nuclear energy and from the use of radioactive materials in industrial applications, research and medicine. The importance of safe management of radioactive waste for the protection of human health and the environment has been recognized and considerable experience gained in this field.

A factor which contributes to the safe management of radioactive waste is the authorization of waste management activities and waste management facilities by the regulatory body established or designated with the responsibility to carry out the regulatory function with regard to safety and the protection of human health and the environment. It is the responsibility of the regulatory body to organize an authorization process (licensing process) that may follow a sequence depending on the legal framework and the facility or activity. The decision of the regulatory body is normally based on the licence application of a legal person responsible for the waste management facility or the activity. Although the content of the licence application and the documentation to be submitted in support to the application that corroborate the application is generally defined in the IAEA Safety Standards and Safety Guides, the applicant is faced with some difficulties in preparing this documentation.

This publication provides guidance to the operators (licensees) of radioactive waste processing and storage facilities on the detailed content of documents which should be submitted to the regulatory body in support of the application for authorization and the ways of obtaining the required information.

This publication has been developed through a series of Consultants' Meetings and a Technical Committee Meeting held in Vienna. The IAEA wishes to express its appreciation to all those individuals that took part in the preparation and finalization of this publication. The officer at IAEA responsible for this publication was A. Kahraman of the Division of Nuclear Fuel Cycle and Waste Technology.

EDITORIAL NOTE

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SUMMARY

The IAEA provides support to its Member States in the development of waste management competence and technical capabilities by publishing various reports on waste management methods and technologies, by providing the reference design of the waste processing and storage, and by providing direct assistance through various Technical Cooperation projects. As a result of the IAEA support and national commitments, waste processing and storage facilities are being established in many developing Member States.

According to IAEA's recommendations and national legislation such new facilities need to be authorized or licensed. In the same time there are a lot of waste processing facilities around the world that were put in operation a long time ago without a proper authorization but are obliged now to obtain an authorization in accordance with current national requirements and also the facilities requiring revalidation of the existing licence.

The IAEA's Safety Standards requires that the prime responsibility for safety shall be assigned to the operator. According to the International Basic Safety Standards (BSS) for Protection against Ionizing Radiation and for the Safety of Radiation Sources, the legal person responsible for any radioactive waste management facility shall apply to the regulatory body for an authorization which shall take the form of a licence. The application shall be supported by relevant information. The nature of this information and the types of documents containing the information will depend on the nature of the facility and the risks it presents. At each stage of the authorization process the operator is required to demonstrate to the satisfaction of the regulatory body that the facility can be operated without giving rise to undue radiological risks to workers, the public and the environment. To this end, the operator should be able to demonstrate that he has adequate organization, management, procedures and resources to discharge its obligations and, as appropriate, its liabilities. The totality of the documentation which the operator uses in making this demonstration, some of which may not be in the initial formal submission, should cover all appropriate topics, depending on the stage of the authorization process and the nature of the facility.

Some operators of radioactive waste management facilities experience difficulties in obtaining an authorization for operation or even fail to get it. Most common reasons for such difficulties and failures are listed below:

- The waste operator is not updated to the current legal national framework, international recommendations and tools and methods to prepare requested information (e.g. safety assessment, environmental impact assessment).
- Insufficient human resources and funds do not allow the operator to carry out necessary studies himself or contract outside organizations to assist in the preparation of the application for authorization. As a result, the operator fails to submit to the regulatory body a complete set of required documents or the submitted documents may contain inaccurate data.
- The Management System of the operator is not accepted by the regulator due to lack of comprehensiveness that may lead to safety problems and non-conformities.
- The cost estimates of waste management facilities are not available or inaccurate. The liability of waste management operators is not assessed properly.

The objective of this publication is to describe the authorization process, including the responsibility of the operator of a radioactive waste management facility for the preparation of an application for authorization, and provide advice to the operators of radioactive waste processing and storage facilities for preparing an application for authorization of operation of such facilities. The publication is concerned with the detailed content of documents, which

should be submitted to the regulatory body by the operator in support of the application for authorization, and the ways of obtaining the required information. It also provides guidance on the organization of work needed to prepare the application for authorization.

The publication covers all predisposal waste management facilities and practices for receipt, pretreatment (sorting, segregation, characterization), treatment, conditioning, internal relocation and storage of low and intermediate level radioactive waste, including disused sealed radioactive sources. The publication contains an Annex presenting the example of a safety assessment for a small radioactive waste storage facility.

Facilities dealing with both short lived and long lived low and intermediate level waste generated from nuclear applications and from operation of small nuclear research reactors are included in the scope. Processing and storage facilities for high activity disused sealed sources and sealed sources containing long lived radionuclides are also covered. The publication does not cover facilities processing or storing radioactive waste from nuclear power plants or any other industrial scale nuclear fuel cycle facilities. Disposal facilities are excluded from the scope of this publication.

Authorization process can be implemented in several stages, which may start at the site planning and the feasibility study stage and will continue through preliminary design, final design, commissioning, operation and decommissioning stages. This publication covers primarily the authorization needed to take the facility into operation.

1. INTRODUCTION

1.1. BACKGROUND

Radioactive waste management is a subject that has received considerable attention in the Member States in recognition of its importance for the protection of human health and the environment from adverse effects of radiation associated with radioactive waste.

Fundamental safety principles for the management of radioactive waste have been developed and agreed at the international level [1]. They form the basis for the corpus of internationally endorsed safety standards for radioactive waste management developed by the IAEA [2, 3] and also for the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management [4].

A range of radioactive waste types is generated in the nuclear industry and as a result of the application of radionuclides in research, industry and medicine. There is a good degree of consensus on the methods for managing most of the waste from the nuclear fuel cycle and other waste types. The optimal choice of the management method must take into account the magnitude and longevity of the risks posed by the waste type as well as the practicability of the solutions, in terms of, inter alia, their availability and their cost.

The IAEA provides support to its Member States in the development of waste management competence and technical capabilities by publishing various reports on waste management methods and technologies [5–9], by providing the reference design of the centralized waste management facilities [10, 11], and by training the waste management personnel. As a result of the IAEA support and national commitments, waste processing and storage facilities have been or are being established in many developing Member States.

According to the International Basic Safety Standards (BSS) for Protection against Ionizing Radiation and for the Safety of Radiation Sources [12], the legal person responsible for any radioactive waste management facility shall apply to the regulatory body for an authorization

which shall take the form of a licence. Any legal person applying for an authorization shall submit to the regulatory body relevant information necessary to support the application [12].

The requirements in respect of the documentation to be produced by the operator or by the regulatory body at the various stages of the authorization process are set up in Ref. [2]. Furthermore, the IAEA Safety Guide No. GS-G-1.4 [13] provides recommendations for regulatory bodies and operators on the preparation of the documentation for regulatory processes for nuclear facilities, and on how to ensure that such documentation is of sufficient quality and provides correct information in an appropriate way to serve its intended purpose.

However, experience has shown that some operators of radioactive waste management facilities experience difficulties in obtaining an authorization for operation or even fail to get it. Most common reasons for such difficulties and failures are listed below:

- The waste operator is not updated to the current legal national framework, international recommendations and tools and methods to prepare requested information (e.g. safety assessment, environmental impact assessment).
- Insufficient human resources and funds do not allow the operator to carry out necessary studies himself or contract outside organizations to assist in the preparation of the application for authorization. As a result, the operator fails to submit to the regulatory body a complete set of required documents or the submitted documents may contain inaccurate data.
- The Management System of the operator is not accepted by the regulator due to lack of comprehensiveness that may lead to safety problems and non-conformities.
- The cost estimates of waste management facilities are not available or inaccurate. The liability of waste management operators is not assessed properly.

1.2. OBJECTIVE

The objective of this publication is to provide advice to the operators of radioactive waste processing and storage facilities for preparing an application for authorization of operation of such facilities. The publication is concerned with the detailed content of documents, which should be submitted to the regulatory body by the operator in support of the application for authorization, and the ways of obtaining the required information.

The publication is primarily intended for the operators of new facilities but would also be helpful to the operators who already operate their facilities without a proper authorization but are obliged to obtain an authorization in accordance with current national requirements and also to the operators of the facilities requiring revalidation of the licence.

1.3. SCOPE

The publication covers all predisposal waste management facilities and practices for receipt, pretreatment (sorting, segregation, characterization), treatment, conditioning, internal relocation and storage of low and intermediate level radioactive waste, including disused sealed radioactive sources. Disposal facilities are excluded from the scope of this publication.

Facilities dealing with both short lived and long lived low and intermediate level waste generated from nuclear applications and from operation of small nuclear research reactors are included in the scope. Processing and storage facilities for high activity disused sealed sources and sealed sources containing long lived radionuclides are also covered. The publication does not cover facilities processing or storing radioactive waste from nuclear power plants or any other industrial scale nuclear fuel cycle facilities.

Authorization process can be implemented in several stages, which may start at the site planning and the feasibility study stage and will continue through preliminary design, final design, commissioning, operation and decommissioning stages. This publication covers primarily the authorization needed to take the facility into operation.

Since the detailed content of documentation submitted to the regulatory body is facility-specific and specific to the particular licensing process that a Member State has, the set of documents and requirements for their content is based on the IAEA recommendations expressed in numerous Agency's Safety Reports and are of generic character.

1.4. STRUCTURE

Section 2 provides the scope of the authorization process, including the responsibility of the operator of a radioactive waste management facility for the preparation of an application for authorization. This section is based on the requirements established in the related IAEA's safety publications [2, 13, 14].

Section 3 provides guidance on the organization of work needed to prepare the application for authorization.

Section 4 addresses information and documents needed in support of the application for authorization.

Section 5 presents guidance on the preparation of the required information.

Section 6 contains the conclusions.

The publication contains an Annex presenting the example of a safety assessment for a small radioactive waste storage facility.

2. THE AUTHORIZATION PROCESS

2.1. GENERAL CONSIDERATIONS

The IAEA Safety Standard GS-R-1 Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety [2] requires that in each Member State where radioactive waste is generated "…a legislative and statutory framework shall be established to regulate the safety of facilities and activities. A regulatory body shall be established and maintained, it shall be effectively independent of organizations and bodies charged with the promotion of nuclear technologies or responsible for facilities or activities".

The Safety Standard also requires that the prime responsibility for safety shall be assigned to the operator. Organizations, which generate radioactive waste, shall have responsibility for the safe management of radioactive waste that they produce. The regulatory body shall have responsibility for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides. In fulfilling its statutory obligations, the regulatory body "shall provide for issuing, amending, suspending or revoking authorizations…" Authorization is the principal mechanism connecting the legal framework of the regulatory system (the laws and regulations) with the responsibilities of the principal parties that are affected by the regulatory system (the regulatory body and the operator) [13]. Authorization is a written permission for an operator to perform a specified activity or a set of activities dealing with the siting, design, construction, commissioning, operation, decommissioning or closure of a facility. It also

establishes, directly or by reference, conditions governing the safe performance of these activities. Authorization could consist of, for example, a licence, certification or registration.

In order to discharge the responsibility for authorization, the regulatory body establishes a process for dealing with applications for granting an authorization. To obtain an authorization for a facility, the operator shall submit adequate information including a detailed demonstration of safety to the regulatory body for its review and assessment in accordance with clearly defined procedures. Approval of an application by the regulatory body is formalized by granting an authorization to the operator in accordance with the laws and regulations of the Member State concerned. Once it has been issued, the terms of the authorization, including any conditions attached thereto, are binding on the operator unless and until amended, suspended or revoked by the regulatory body.

The authorization process for a predisposal waste management facility, the safety requirements and the supporting documentation for an authorization application should be in accordance with the relevant national legislation. Although the details in the national legislation may differ, they should be in line with good international practice as outlined in IAEA and other international standards.

The application for an authorization should comprise:

- A demonstration of the required level of safety of the facility.
- A demonstration of the protection of the environment both in the short and long term perspective.
- An assurance that the generation of secondary radioactive waste in the facility is kept to the minimum practicable.
- A demonstration that account is taken of interdependencies among all steps in radioactive waste management.
- An assurance that any processing of radioactive waste will be compatible with the anticipated type and duration of the storage and the need for retrievability of the radioactive waste from storage.
- The cost estimates of the waste management facilities and the liability of the operator with regard to the management of radioactive waste in the long term.
- An assurance that account is taken of anticipated waste arisings, accountability of waste, disposal options and safety considerations.
- An assurance of acceptance/tolerance of the facility by the public.
- An assurance of adequate physical security.

Review and assessment by the regulatory body give rise to a series of decisions in the authorization process. Not all of these decisions necessarily result in the granting of a formal authorization to the operator. However, at the conclusion of one or more stages, the regulatory body takes an official action which may result in the granting of an authorization.

The granting of an authorization does not restrict or preclude subsequent amendment, suspension or revocation of that authorization by the regulatory body within the period of its validity. A request for an amendment may be initiated by the operator, or an amendment may be imposed by the regulatory body in the interest of safety. A modification of the authorization may be desirable or necessary as a result of proposed changes relating to the facility, experience from the facility itself or elsewhere, or technological advances, or as a consequence of research and development relating to nuclear safety [14].

The types and number of authorizations to be issued in connection with a particular facility vary between Member States. Some Member States, for example, issue only one authorization, followed by various amendments, additions and modifications, while others

issue several authorizations at a number of intermediate points from the site evaluation to decommissioning. National legislation may require a separate licence for all major components of a system, e.g. treatment of liquid waste, treatment of solid waste, and interim storage of conditioned waste, while others may permit or require that all components are integrated into one single licence. In the first case, proportionally more effort must be taken to ensure that the components are properly interlinked and compatible, but it may be easier to process the individual licences. In the second case, integration of the different components into one integrated system is easier, but the application may be more difficult to review.

Despite the above differences in practice, several points can be identified, corresponding to the major stages of the authorization process, at which significant regulatory decisions are usually made and documents issued. It should be noted that some of these stages may be combined, depending on the nature of the facility and the laws and regulations of the State concerned.

2.2. THE OVERALL ROLE OF THE REGULATORY BODY

The overall role of the regulatory body in relation to the safety of radioactive waste management is to establish safety requirements and control or ensure by supervision the compliance with these requirements. As it has already been said, the regulatory body has the responsibility to establish an authorization process for radioactive waste management facilities. The specific responsibilities placed on the regulatory body in relation to the planning of the authorization process for radioactive waste management facilities and activities are to:

(a) establish conditions for authorization (licence);
(b) establish a process for dealing with applications for issuing of an authorization;
(c) establish a process for changing conditions of an authorization;
(d) provide general guidance to the operator on meeting requirements for documentation;
(e) provide detailed guidance, including guidance on the type and content of, and timing for, documentation to be presented by the operator (if it is not spelled out in the regulations in detail).
(f) define and make available to the operator the principles and associated criteria on which its judgments and decisions are made.

The analysis of the authorization process in many developing countries has revealed that some regulatory bodies fail to provide detailed guidance on the type and content of documentation to be submitted by the operator in support of the licence application. In this regard, this publication may serve as guidance not only to the operators but also to the regulatory body.

The fact that some developing Member States have both the operating function and the authorizing function within the same organization does not, in principle, change the above responsibilities. Since such a situation is often the result of a too small national organization to justify two independent organizations, there is a need to find practical solutions to the situation, but the aim should always be to strive for as much independence as possible.

2.3. RESPONSIBILITIES OF THE OPERATOR

The operator should be responsible for submitting documentation and information in support of an application for authorization as required by the regulatory body. The nature of this information and the types of documents containing the information will depend on the nature of the facility and the risks it presents as well as on the applicable national requirements.

At each stage of the authorization process the operator is required to demonstrate to the satisfaction of the regulatory body that the facility can be operated without giving rise to undue radiological risks to workers, the public and the environment. To this end, the operator should be able to demonstrate that he has adequate organization, management, procedures and resources to discharge its obligations and, as appropriate, its liabilities. The totality of the documentation which the operator uses in making this demonstration, some of which may not be in the initial formal submission, should cover all appropriate topics, depending on the stage of the authorization process and the nature of the facility [13].

2.4. IMPLEMENTING THE AUTHORIZATION PROCESS

In implementing the authorization process the regulatory body will [14]:

(a) review and assess applications from operators for the authorization of waste management activities and/or waste management facilities;
(b) review and assess environmental impacts and safety;
(c) communicate with, and provide information to, other competent governmental authorities, international organizations and the public;
(d) conduct compliance assurance activities including inspections of the facilities in which waste is or will be managed;
(e) require operators to take corrective measures where necessary;
(f) issue, amend, suspend or revoke authorizations; and
(g) provide an explanation of the reasons for the rejection of a submission.

A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment will be performed by the regulatory body in order to determine whether the facility complies with the relevant safety objectives, principles and criteria. In doing this, the regulatory body will acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based and the operating principles proposed by the operator. Review and assessment are performed by the regulatory body in accordance with the potential magnitude and nature of the hazard with the particular facility [14].

It is recognized that the licence, when granted, will normally include licensing conditions that have to be met by the operator when the licence is in place. Such a requirement could be that all amendments or modifications of the facility as well as significant organizational changes will require the approval of the regulatory body before implemented.

Once the facility is licensed and under operation, the regulatory body may conduct inspections to satisfy itself that the operator is in compliance with the conditions set out in the licence; facilities and equipment meet all necessary requirements, relevant documents and instructions are available, and persons employed by the operator possess the necessary competence for the effective performance of their functions. During these inspections the operator may be required to provide assistance to the regulatory body by explaining and clarifying the information contained in the documents supporting the licence application.

Enforcement actions are applied as necessary by the regulatory body in the event of deviations from, or non-compliance with, conditions and requirements.

The basic safety principles [1] and the safety requirements [2, 3] are the same for managing any amounts and types of radioactive waste. In facilities where only small quantities of radioactive waste are generated there may be limited knowledge and competence among the staff on its proper management. The safety culture, to the degree it exists, may not be particularly focused on radioactive waste management. However, when handling small

quantities of low level waste the risk potential is small, and especially when handling short lived waste, the impact on the environment may not be very significant.

2.5. INTERACTIONS OF THE OPERATOR WITH THE REGULATORY BODY

The operator and the regulatory body should establish formal relations based on independence and mutual respect [2]. Proper channels of communication between the operator and the regulatory body should be established.

The operator, with its responsibility for the safety of the facility, may be the only organization among those involved in the manufacture, construction, installation, operation and safety analysis of the facility that will have direct relations with the regulatory body. In this case, the operator should represent all its contractors in formal dealings with the regulatory body, including the submission of documents and attendance at meetings. As review and assessment progress, it may be necessary for the regulatory body, with the knowledge of the operator, to have direct contact with a contractor. These contacts should not diminish the responsibility of the operator for the safety of the facility.

The operator should submit its documentation early enough to allow the regulatory body to proceed in a timely manner with its review and assessment.

In all stages of the authorization process, the operator and the regulatory body should continue to hold meetings to discuss topics such as the bases for proposed changes, in advance of making formal submissions, or to discuss matters already under consideration. A formal programme of meetings at different levels of management may be established between the regulatory body and the operator, in order to promote good relations and to afford the possibility of announcing potential changes or initiatives, thus facilitating future planning. Written records should be kept of such meetings, and of any decisions or agreements reached.

2.6. INTERACTIONS WITH OTHER GOVERNMENTAL AUTHORITIES

In addition to the regulatory body, other governmental authorities may participate in the authorization process in accordance with national legislation, regulations and practices. It is the responsibility of the operator to establish and maintain liaison throughout the lifetime of the facility with other governmental authorities as appropriate. The nature of the relation between the operator and other governmental authorities is determined by national legislation.

Areas in which such authorities might participate in the authorization process should be identified. These areas may include:

- environmental protection;
- public and occupational health;
- public liability issues (including implementation of national regulations and international conventions concerning third party liability);
- security, physical protection and/or safeguards;
- use of water resources and consumption of food;
- land use and planning;
- fire protection;
- safety in the transport of dangerous goods;
- law enforcement;
- civil engineering structures and buildings, and electrical and mechanical equipment;
- emergency preparedness.

The authorizing process including the interrelationship of different parties involved is shown graphically in Figure 1.

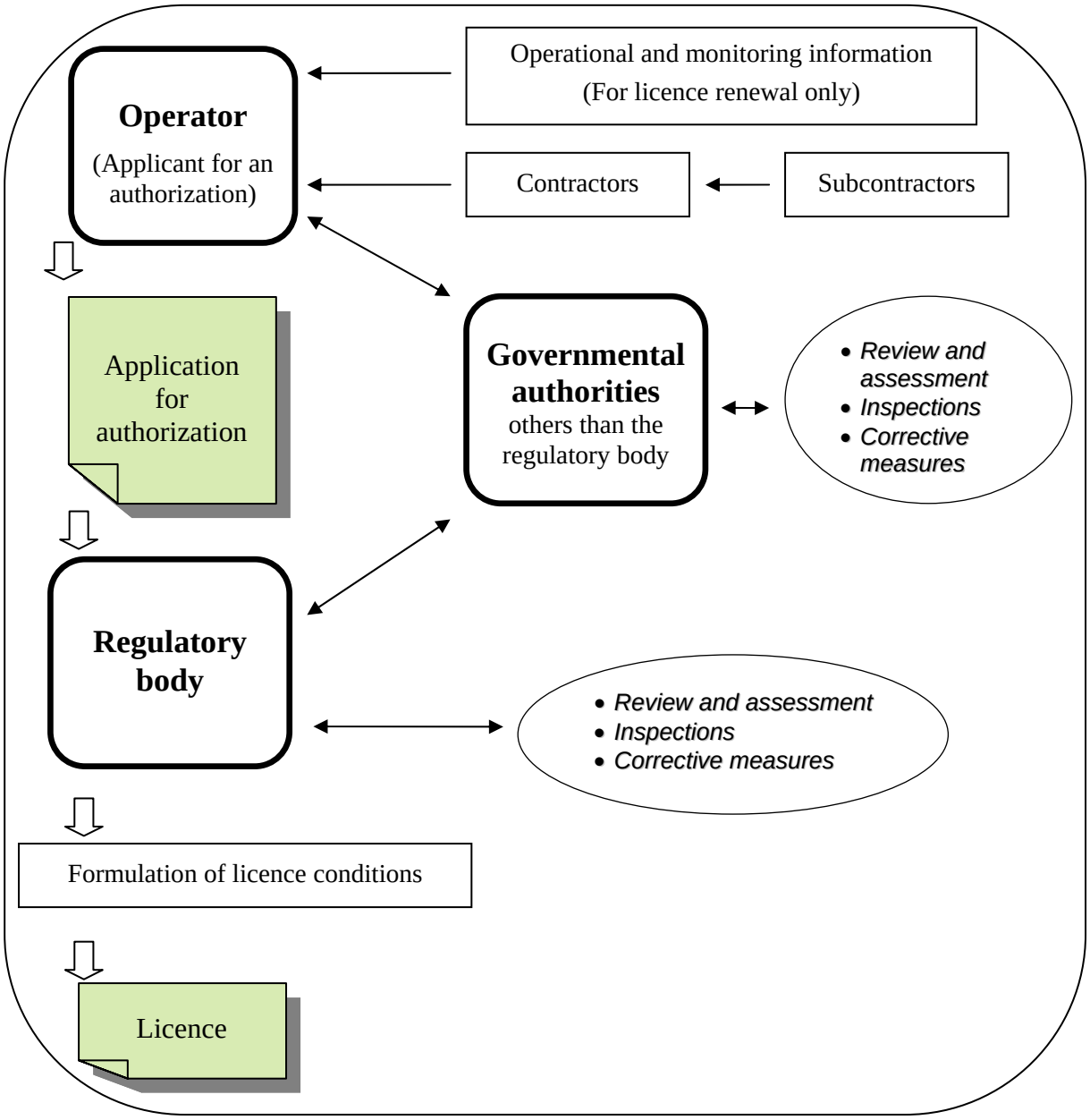

FIG. 1. Correlated interactions during authorization process

2.7. LICENCE DOCUMENT

A licence is the principal document produced by the regulatory body that relates the legal framework of the regulatory system (i.e. laws and regulations) to the responsibilities of the operator of a facility at each stage of the authorization process. Licence conditions are incorporated into the licence, as necessary, in order to impose additional specific obligations with the force of law.

The format of a licence issued by the regulatory body will depend upon the content of the authorization and the conditions deemed necessary by the regulatory body for a given stage of

the authorization process in accordance with national legal procedures. The format of a licence will vary not only among Member States, but also within a state, from stage to stage, and from licence to licence for a given stage. The IAEA Safety Guide on Documentation for Use in Regulating Nuclear Facilities [13] provides general considerations for use by a state in determining which licence formats best meet its needs. According to this Safety Guide the licence should contain information such as:

- **Statutory authority**. The licence should explicitly refer to the laws and regulations on which it is based.
- **Issuing authority**. The licence should identify the official designations of those who are empowered by law or regulation to issue the licence, whose signature and stamp will appear on the licence, and to whom the operator will be accountable under the terms of the licence.
- **Fulfilment of requirements**. The licence should include a summary statement that all legal and technical requirements in respect of safety have been fulfilled and that the proposed activities can be carried out without undue radiological risk to workers, the public or the environment.
- **Documentary basis**. The licence should identify the documents provided by the operator in support of the application and those prepared by staff of the regulatory body in the review and assessment process, which together forms the basis for issuing the licence.
- **Relationship to other licences**. The licence should indicate whether it is contingent upon a prior authorization or is a prerequisite for a future authorization.
- **The operator**. The licence should contain a precise identification of the individual or organization both legally responsible for the licensed activity and in day to day control of the facility.
- **Period of authorization**. The licence should state an effective date of authorization. It may also include a termination date, which may be based on a fixed term such as one or two years. Alternatively a period may be stated over which the assumptions underlying the licensing decision will remain valid and at the end of which the basis for licensing will be re-examined.
- **Licensed activity**. The licence should clearly describe in sufficient detail the nuclear facility, its location and the activities authorized.
- **The operator's responsibility for compliance**. The licence should contain an appropriate declaration that the operator has the responsibility for compliance with the legal requirements, regulations and conditions referenced or contained in the licence or in other references, if applicable. The licence should also state that this responsibility is not transferable.

Licences should state explicitly, or should impose by reference or attachment, all conditions as determined by the regulatory body, which are obligations with which the operator is required to comply [13]. Laws and practices relating to licensing vary between Member States. In some States, conditions are specified in the law and in regulations of the regulatory body, and are merely referenced in the licence, while in other states some or all conditions are stated explicitly in the licence.

In addition to those general licence conditions which are applicable to all licences, there are some conditions that are relevant only to licences issued at certain stages of the authorization process. As authorizing operation may follow authorizing commissioning, the conditions of a commissioning licence (if required) should be taken into account while the conditions in the operation licence are formulated.

In authorizing commissioning of a nuclear facility, the regulatory body may specify a number of conditions, including the following [13]:

- Commissioning shall be carried out in accordance with a programme approved by the regulatory body.
- Completed structures, systems and components important to safety shall only be put into service once they have been inspected, tested and approved as being in accordance with the terms of the licence.
- The regulatory body may require that appropriate physical security measures be in effect before radioactive material is brought into the facility.
- Radioactive material shall only be brought onto the site with regulatory authorization.
- Beginning with the introduction of radioactive material into the facility, the operator shall operate the facility only under the control and supervision of authorized personnel using written procedures, in accordance with the operational limits and conditions approved by the regulatory body. Any changes made to these procedures, limits and conditions shall be approved by the regulatory body prior to their implementation.
- The operator shall have an approved emergency plan, co-ordinated with the other authorities involved in emergency preparedness.

In authorizing routine operation, the conditions imposed for commissioning should be appropriately amended in the light of commissioning results. The regulatory body may add conditions such as the following to the licence, as necessary [13]:

- The operator shall not operate the facility outside the design limits authorized by the regulatory body.
- The operator shall have a procedure for modifications to be approved by the regulatory body in order to ensure that no part of the approved facility that is important to safety will be modified without the prior approval of the regulatory body.
- The operator shall ensure that the facility is subjected to in-service inspection and testing, to be carried out as specified for structures, systems and components important to safety, to a time schedule approved by the regulatory body.
- The operator shall ensure that the maintenance of safety related equipment and systems is carried out in accordance with a schedule approved by the regulatory body.
- Only changes given prior approval by the regulatory body shall be made to the approved arrangements, schedules, procedures and rules.
- The operator shall ensure that the facility is operated only under the control and supervision of authorized personnel in adequate numbers that are acceptable to the regulatory body.

3. ORGANIZATION OF THE DOCUMENTS PREPARATION

The goal of the facility top management responsible for preparing an authorization application is to organize a process for collecting and compiling a comprehensive package of relevant documents with justification of proposed activities and demonstration of capabilities of the operator to comply with the regulatory requirements.

As the eventual scale and type of predisposal waste management facilities vary, there could be different approaches for organization of the work for the preparation of an authorization application. Consequently, this section provides some general advice to the operators of waste processing and storage facilities, but specific regulatory requirements and the infrastructure within a country may require different approaches.

3.1. MANAGING

Managing within the operator of the preparation of all necessary documents is an important part of the process. Procedures should be developed which establish the general method for the development of required documents. These procedures should cover the composition of working groups and the drafting and approval procedure, including the assurance of quality and legal support.

Consideration should be given to assigning managerial responsibility to a single individual or organizational unit (e.g. a task leader) with relevant competence. This task leader should be able to prepare the comprehensive terms of references in line with regulatory requirements and to evaluate results of the studies. The task leader, after submission of an application and all supported documents may be involved in discussions with the regulatory body to explain and to justify the proposed activities.

The preparation of application documents should include responsibility for:

(a) planning and directing the preparation process;
(b) preparing the procedures to be followed in accordance with the overall Management System (see Section 4.2);
(c) co-ordinating all information exchange between the operator and the regulatory body;
(d) making arrangements for liaison with other governmental authorities;
(e) making arrangements for liaison with consultants or contractors;
(f) keeping a log for all documents sent or received;
(g) qualification and training of the personnel engaged in the preparation process.

3.2. RESOURCES

Preparation of documentation for an application will require resources in the areas of finance, human resources, and infrastructure. The financial and human resources needed for this preoperational stage may exceed the demands of the facility when it is in operation. Arrangements to provide the resources for the preparation of documentation should incorporate the demands imposed by the safety, health, environmental, security, quality and economic aspects associated with the full range of activities involved and the potentially long duration of the activities.

The majority of information and documents usually are readily available or could be easily obtained by the operator from different state institutions. For preparing some documents, the operator may seek an advice or hire experts from external organizations as contractors. These contractors may be involved in design, manufacture, construction, installation, maintenance, safety analysis or environmental impact assessments and may themselves have subcontractors. Therefore, in the initial stage of the preparation of an application the manager for these activities should decide, which particular documents shall be prepared or studies be carried out by its own experts or external experts. The applicant should also decide on the scope of in-house training if required, and arrange this training properly. It should be the responsibility of the operator to make arrangements with its contractors to ensure the availability of all necessary information and to maintain linkages and relationships between various experts, especially if more than one organization is involved. Where a contractor is used to prepare the documents, the operator is still responsible for their content and for ensuring that they are adequate and are covered by the Management System.

The reliability, comprehensiveness and quality of information will depend on qualification, competence and practical experience of all persons involved in the preparation of required documents. At all times, they should carry out their assigned work competently and with a

clear understanding of the consequences for safety and environmental protection of their tasks. Additionally, in some Member States, personnel performing work in defined positions important to safety and environmental protection should be authorized (e.g. licensed) as required by the appropriate regulatory body.

In particular cases, the difficulties in preparation of an application and getting approvals could arise due to lack of competence at the level of local authorities, which may be involved in some authorization activities (e.g. construction, engineering, emergency preparedness). These issues should be discussed with the regulatory body and in some cases legal requirements need to be changed to allow central institutions to make decisions instead of local authorities. These cases should have special handling to avoid conflicts and lack of public acceptance.

As predisposal management may include long periods of waste storage prior to disposal, during which understanding and knowledge in certain areas will continue to grow, therefore the capabilities to manage the preparation of an application should be continuously maintained in the organization. Owing to changes in the national infrastructure, international binding requirements and recommendations the legal requirements for authorization may change, therefore the operator should be ready to review periodically the activities at the facility and to incorporate the knowledge and experience that has been gained in relation to new processes, technology, changes of personnel skills, and other factors, in a new application for the licence when needed.

A separate challenge could be the public acceptance of the neighbouring country, if the facility is (will be) located nearby the national borders. As public acceptance activities and site selection are usually performed within the country, there could be disagreement with a neighbouring state due to some main reasons:

- Other countries usually do not benefit from the proposed activities.
- During the site selection the operator has used criteria (e.g. density of population, environmental risks and limiting scenarios) only for the state where facility will be established, but not across the border.
- The environmental impact assessment and public hearings related to these studies are done without involvement of the public (their representatives, NGOs etc.) from a neighbouring country.

3.3. PRELIMINARY AUTHORIZATION

In some cases a preliminary authorization by the regulatory body (‘conceptual authorization’) may be needed for new facilities or even for certain significant modifications of an existing facility. By applying for such a preliminary authorization the applicant could reduce investments in the preparation of a full scope application, which may be not accepted in principle.

In some cases it might be preferable to choose a licensed prototype facility (locally available or in a country with similar legal requirements) and to organize consultations with its relevant staff before planning the work and giving assignments for the preparation of an application. By such an approach the work plan and assessment of needed resources for planned activities could be prepared faster. Also, less non-predicted changes and additional expenses would be needed.

With some exceptions, similar approach could be useful for the preparation of applications for renewal or extension of an existing licence. Usually in such cases the scope of work for the preparation is more limited — there is no need to re-submit information, which has not changed since the last application.

More information might be prerequisite for some countries for the renewal or extension of the licence. This information is obtained from the monitoring programmes and operational experiences of these countries. Safety assessment and, in certain circumstances, environmental impact assessment might be updated in parallel with the renewal or extension of the licence. The last issue should be considered especially if significant changes are planned such that new environmental risks or new modifications to adopted scenarios would be introduced.

3.4. INTEGRATED MANAGEMENT APPROACH

It is a common practice that radioactive waste is managed by a series of organizations that carry out the sequence of required processing steps. For example, the waste generated by one organization may be transferred to a predisposal waste management facility and then, after treatment and conditioning, the waste may be eventually transferred to the repository. So predisposal waste management should take into account the characteristics of incoming waste and must comply with the waste acceptance criteria (existing or eventual) for disposal.

Organization of the work for the preparation of an authorization application is just one part of the entire Management System (see Section 4.2), which is required from the operator. The operator may benefit from such a system because it will provide necessary information for operation of the waste management facility and for safety and environmental impact assessments. From another side, when the licence is to be renewed or modified, existence of the integrated Management System will provide confidence to the regulatory body that the performance of the predisposal waste management facility and activities will meet the requirements and both operator and regulator will be able to maintain public confidence on these practices.

4. PREPARATION OF THE REQUIRED DOCUMENTS FOR LICENCE APPLICATION

In applying for a licence, the operator should provide all relevant information describing the approach to safety in order to demonstrate that the facility will not present undue radiological risks to workers, the public and the environment. The relevant information should be presented in such a way that the regulatory body can conduct the review and assessment process without needing to seek further information or clarification [14].

Documents of different types should be prepared by the operator in discharging its responsibilities with respect to the safety of the facility. Some of these documents have to be submitted formally to the regulatory body for review and assessment in the course of the authorization process. Other documents are reports that should be submitted to the regulatory body periodically, or event, incident or accident reports to keep the regulatory body fully informed of the conditions prevailing at the facility. A third type of document is for internal use by the operator but should be made available upon request to the regulatory body to ensure its complete understanding of the design and operation of the facility, so that it can confirm that the requirements established in the regulations and licensing conditions have been fulfilled.

Information to be submitted to the regulatory body for review and assessment in the course of the authorization process could be categorized as ***basic information***, information regarding

*the **Management System***[1] of the applicant and information on other plans and programmes in ***support of safety activities of the operator*** [13]. The level and depth of the actual information provided will vary within each country and will depend on the risks associated with the processes, the complexity of the process and national legislation. For a facility processing or storing small quantities of radioactive waste it could be appropriate to restrict the information provided to a level to be determined by the applicant, in discussion with the regulatory body. It is emphasized that the details listed below may contain requests for information, which in some countries does not need to be provided in order to obtain a licence.

4.1. BASIC INFORMATION

The basic information to be provided should cover the following issues:

- a description of the site;
- amounts and characteristics of radioactive waste;
- a description of the facility; its systems and components;
- modes of operation;
- applicable regulatory documents;
- demonstration of safety, including the classification of equipment, systems and components, the application of the defense in depth principle, and the use of multiple barriers to prevent radioactive releases;
- demonstration of environmental protection.

4.1.1. Description of the site

The general location of the facility may have an important influence on the likely pathways for release of radionuclides to the biosphere and the extent to which factors such as climate and ecological change can influence the impact of such releases.

Information related to the site, with particular emphasis on factors important to radiation safety and environmental protection, and emphasizing those site characteristics, which may influence the operation of the waste processing or storage facility, is required to confirm the acceptability of the site for its intended purpose.

It should also be demonstrated that the facility is suitably located in relation to other existing facilities that interact with the facility to be licensed. It should give the baseline situation regarding, for example, environmental contamination. The description of the site should also give the reason to choose this site for the intended facility.

A description of the site should contain the following detailed information:

- Ownership of the site, including where applicable, tenancy agreements and the rights to the use of facilities on the site for the whole period of operation and decommissioning activities.
- Maps and plans, which show the site and the locations of the buildings and facilities on the site.
- Results of baseline measurements on the site:

[1] This publication uses the term ‘Management System’ instead of ‘Quality Assurance’. The term Management System reflects and includes the evolution in the approach from the initial concept of ‘Quality Control’ (controlling the quality of products) through ‘Quality Assurance’ (the system to assure the quality of products) and ‘Quality Management’ (the system to manage quality). The ‘Management System’ is a set of interrelated or interacting elements that establishes policies and objectives and which enables those objectives to be achieved in a safe, efficient and effective way [15].

- Radiological surveys carried out prior to use of the site for waste management purposes or prior to licensing. In the case of renewal of the licence, in addition, a complete radiological survey report for the whole operation period should be prepared.
- Physical characteristics, e.g:
  - meteorology (climate, precipitation, potential for extreme weather phenomena, wind and atmospheric dispersion characteristics);
  - hydrogeology and hydrology (location, extent and interrelationship of important hydrogeological units (stations), average flow rates and prevailing directions of the surface and groundwater flows, information on the regional and local water tables and their seasonal fluctuations);
  - geology (stratigraphy, lithology and mineralogy, structural characteristics; geotechnical characteristics);
  - seismology (recent or historic evidence of active faulting, tectonic processes or igneous activities, historical earthquakes, potential for natural events such as volcanic eruptions).
- Ecological resources, e.g.:
  - fisheries and aquatic biology;
  - wildlife and forests;
  - protected areas and protected nature territories;
  - coastal resources.
- Economic development, e.g.:
  - industries;
  - infrastructure facilities (e.g. water supply, power sources and transmission, sewerage, flood control);
  - arrangements for transportation of waste to the site (roads, harbours, airports, and navigation);
  - current use of lands and resources for traditional purposes by indigenous people;
  - agricultural and mineral development, tourism facilities.
- Social and cultural resources, e.g.:
  - population and communities (e.g. numbers, locations, composition, employment);
  - health facilities;
  - education facilities;
  - socioeconomic conditions (e.g. community structure, family structure, social well being);
  - physical or cultural heritage;
  - structures or sites that are of historical, archaeological and architectural significance.

4.1.2. Waste acceptance criteria

The applicant is required to provide a description of the waste to be processed and/or stored at the facility. This information is needed to demonstrate to the regulatory body that the expected primary and secondary (generated during processing of the primary waste) waste is compatible with the design basis of the facility and can be processed and/or stored in a safe way.

The total amount, activity and other characteristics of radioactive waste to be accepted by the applicant for processing or storage shall be defined in so called waste acceptance criteria

(WAC). Waste acceptance criteria are used to identify, control and document the type and quantity of the radioactivity, as well as other physical and chemical properties of the waste. Waste acceptance criteria are generally site or facility specific and they should be developed at the design stage of the facility and submitted to the regulatory body as part of the licence application. The criteria for acceptance of waste for processing will differ from the WAC for storage. If waste is sent to a processing facility, both the original waste generator and/or the operator of the processing facility should respect the storage waste acceptance criteria before producing the waste packages.

Ideally, the waste acceptance for storage should incorporate the waste acceptance criteria for disposal if a repository is available. Waste acceptance criteria are derived from assumptions of safety and performance assessments of the disposal facility. Establishment of WAC is the responsibility of the disposal facility operator in conjunction with the relevant national authorities/regulatory bodies. Verification of compliance of radioactive waste with WAC constitutes the primary method by which the operator of the waste disposal facility ensures the long term performance of the repository. To accomplish this task, the releases of radionuclides to the environment must be limited and controlled, and environmental and human health protection goals realized, by the proper design of the waste package and the disposal facility.

There is a situation when waste is processed and waste packages are produced in the absence of a disposal facility and therefore no applicable WAC are available to guide the design and production of the packages. In this case the packages may be produced and fully characterized in accordance with the best engineering assumptions based on the experience and practice of other Member States. In such circumstances it is inevitable that the storage facility will develop a set of acceptance criteria of their own for waste packages generated under these conditions.

In addition, transport regulations place a set of overlapping criteria on the waste packages which will be transported from production to storage or from storage to disposal. These include surface dose rate, surface contamination limits, weight, size, total activity and structural integrity requirements. This means that the WAC constitute an agreement among the waste generator, transportation organization, and waste storage or disposal facility operator regarding the minimum characteristics of each waste package produced for storage and/or disposal. Meeting these criteria determines how the waste packages will perform under conditions of storage, transport, and ultimately emplacement in a disposal facility.

New facilities should not accept any waste that is not adequately characterized or which does not meet the WAC. Compliance of waste packages with WAC should be verified immediately upon receipt of the waste. Waste characterization should begin at the point of waste generation by establishing a file containing detailed information on the waste. This original waste characterization information must be provided to the processing facility, and this is the responsibility of the waste generator to demonstrate compliance of the waste with WAC. As information is gained during processing operations (e.g. from testing and inspection), this information should be added to the file needed for full characterization of the waste and provided to the storage facility operator.

The applicant should demonstrate that it will be able to determine the characteristics of radioactive waste changed as a result of processing in order to submit these characteristics to another organization that will successively deal with its management (e.g. a central waste storage facility and/or repository). To comply with this requirement the operator should establish and maintain a waste characterization process together with a tracking or a monitoring programme. Guidance on the waste characterization is provided in Ref. [16]. An independent party should ultimately certify the adequacy of the characterization data.

Some waste packages may not be capable of meeting some or all of the identified waste acceptance criteria for storage. This can be the case for waste that has been in small quantities, for which all the required information for acceptance cannot be provided. Acceptance of these waste packages for storage cannot therefore rely on pre-established requirements, such as waste acceptance criteria. A 'case by case' approach should be adopted, using all available information and taking into consideration the number of waste packages concerned. If further non-compliance with the criteria is the consequence and safe storage would not be possible, the determination has to be made that such waste requires additional treatment, characterization, conditioning, etc.

4.1.3. Waste package specifications

The acceptance of waste for storage requires the waste generator or the operator of a processing facility to provide a specification to the storage/disposal facility operator. The nature and content of the information contained should be sufficient for the store operator to confirm that waste packages conforming to this specification will satisfy the waste acceptance criteria. Confirmation of the conformance of individual waste packages to the requirements of a waste package specification can usually be addressed by the preparation of a data file for each waste package.

Waste package specifications consist of a quantitative description of waste packages prepared for storage/disposal. Separate waste package specifications should be developed for each type of waste package. The intention is to demonstrate that the waste packages will meet the waste acceptance criteria for storage/disposal facilities. Typically, waste package specifications will describe the nature, content and performance of each type of waste package and provide a link between the supporting research and development (R&D) and package production.

4.1.4. Description of the facility, its systems and components

A concise but complete description of the overall waste processing or storage facility should be given. Furthermore, principal design criteria including fundamental engineering design objectives established for the process should be provided. Results of special research and development programmes undertaken to establish the final design should be presented.

This information is needed to demonstrate to the regulatory body that the facility will process or store radioactive waste as described in the application. It should also demonstrate that the functions of the facility could be performed.

Assurance that the generation of secondary radioactive waste in the facility is kept to the minimum practicable could be provided by the selection and control of materials, recycle and reuse, clearance, segregation of different types of waste and materials and implementation of appropriate operating procedures. The applicant should demonstrate that all necessary measures would be undertaken in this regard.

Also, it should be demonstrated that interdependencies among all steps in radioactive waste management have been taken into account. Techniques used at one step will not foreclose alternatives for, or otherwise affect, a subsequent step. To achieve satisfactory the overall safety goal of waste management, component steps must be complementary and compatible with each other. This is especially important where a processing facility seeking an authorization from the regulatory body is planned to deal with only one stage of the waste management system (e.g. treatment), and other steps (e.g. conditioning) are planned to be carried out at a different facility.

A description of the facility should include:

- A layout of the facility showing the location of main components and systems of the facility, the type and dimensions of the rooms (e.g. guardroom, offices, change room) workshops, laboratories, buildings, their location and their inter-links.
- Drawings and plans, which indicate in detail, the locations of other buildings and facilities on the site, including auxiliary facilities.
- A description of waste processing techniques (block and flow charts) that will be applied and the design features that are needed for this purpose (for a waste processing facility).
- A description of storage methods, means for control of primary waste and waste packages and provisions for their handling and retrievability (for a storage facility).
- Demonstration that the expected amounts and characteristics of waste are compatible with the design basis and throughput of the processing/storage facilities.
- A description of the receipt control procedures to ensure that the waste delivered for processing/storage meet waste acceptance criteria established by the facility.
- A description of procedures to be applied for waste, which does not meet the waste acceptance criteria of the facility.
- A description of back end options (e.g. decay storage and release from regulatory control by applying clearance procedures, authorized discharge, or disposal in a licensed repository) for the waste being received on site.
- Waste acceptance criteria (WAC) for disposal if they exist.
- Decontamination means for equipment, floor and walls.
- A description of any auxiliary facilities both on-site and off-site, including those for maintenance and repair of equipment. This may include:
    - an overall layout and design of the ventilation system;
    - a detailed description of the site drainage system (e.g. localization, capacity, control before release or treatment);
    - power supply;
    - service water supply;
    - heating or air conditioning;
    - communication means (e.g. telephone, interphone, informatics);
    - compressed air supply.
- A connection to the ventilation and the liquid drainage systems.
- Measures for control of the integrity and structural stability of the buildings and the facility.
- Results of the baseline radiological surveys carried out prior to operation of the facility.
- Detailed information on the changes made during construction and/or during previous operation.
- Specifications of the equipment and tools suggested by design for waste processing and/or storage:
    - justification of the selection of the equipment with regard to mechanical, chemical, thermal and corrosion resistance, and decontamination features;
    - inventory of each process equipment (e.g. shielded cell, glove box, compactor, tank, filtration system, pumps, valves, piping and containers);
    - objectives, function, capacity and limits;
    - control parameters (e.g. temperature, pressure, level, weight, pH, dose rate).
- A description of safety related features of systems and components including the control of their function e.g.:

- design resistance against mechanical, thermal and corrosion damage, fire and explosion,
- prevention and minimization of radiation exposure and radioactive material releases (shielding, weather protecting features, collecting tanks, features enabling handling and retrievability of waste).

If a national waste management strategy has been established, the proposed functions must be in compliance with that strategy and also in line with internationally accepted practices. When existing buildings and equipment are used, it is appropriate to provide documented information on their history to demonstrate that their integral structures as well as other characteristics (e.g. contamination) are acceptable for their intended purpose.

4.1.5. Modes of operation

The applicant is required to submit information on the proposed operational conditions and limits for the safe operation of the waste management facility. This information is needed in order to allow the regulatory body to fully understand the normal operation at the facility and its safety implications.

The following information is required to assess the operational safety of the facility:

- Operating instructions and procedures, which are normally documented in an operating manual, for all functions to be met by the facility (e.g. receipt control, sorting and segregation, volume reduction, waste treatment, conditioning and interim storage of the waste). The operating instructions and procedures should be prepared for each category of radioactive waste (liquid, solid, disused sealed sources, etc.).
- Assessments carried out to demonstrate if the facility is still operating within its original design basis (in the licence renewal process).
- A description of any conditions or limitations of the facility and what steps (including operating rules) are in place to ensure that these will not be exceeded.
- Arrangements for in-service inspection and testing for structures, systems and components important to safety, in accordance with a certain time schedule.
- Arrangements for maintenance of safety related equipment and systems in accordance with a certain time schedule.
- A reporting procedure on serious deviations from normal operation, incidents and accidents (in the licence renewal process).
- Instructions for the personnel on the hazards and precautions.
- Demonstration that operations, which may affect safety, are carried out with adequate supervision.
- Demonstration that every person authorized to be on the site has been familiarized with relevant instructions and received adequate training as regards the risks and hazards associated with the facility and its operation.

For new facilities, the above information should be prepared by the designer in advance and must be available to the operator prior submission of the authorization application. In case of the renewal of the operating licence the information is based on the existing operating practices and experiences.

4.1.6. Applicable regulatory documents

The operator has the responsibility for compliance with relevant statutory and regulatory requirements of the state, stakeholder legal requirements and other requirements established in other codes and standards adopted for use by the organization. Such regulatory documents

provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations. These regulatory documents should be identified, indicated and fully referenced.

Guides, of a non-mandatory nature, on how to comply with the regulations, may provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted by the operator. Such advisory documents should also be identified and referenced to.

4.1.7. Demonstration of safety

The demonstration of safety is a fundamental requirement for all radioactive waste management facilities. The applicant shall provide all relevant information describing the safety approach, basic safety principles, analysis, criteria and standards for operation under normal or accident conditions in order to demonstrate that the radioactive waste management facility will not present undue radiological risks to the site personnel and the public.

The applicant shall demonstrate to the regulatory body how the design and related operational procedures will contribute to the prevention of accidents on the one hand, and to their mitigation on the other. The relevant information shall be presented in such a way as to facilitate for the regulatory body the conduct of the review and assessment process. The demonstration is normally performed by making safety assessment and preparing a safety analysis report. The safety assessment shall show the extent to which the waste management facility can control or accommodate situations related to the various operational stages and accident conditions. The complexity of the safety assessment depends on the potential risk level of the radioactive waste processed or stored and the complexity of the processes involved.

4.1.8. Demonstration of environmental protection

The demonstration of proper protection of the environment can be made by assessing the environmental impact of operation of the waste management facility. The applicant is required to present the results of assessment of the impact of facility operation on the environment. This information is needed in order to demonstrate to the regulatory body that all radiological and non-radiological impacts on the environment from the operation of the facility, including unplanned events are within acceptable limits. This should refer both to the short term environmental impact from short lived radionuclides that might enter the environment and the long term environmental impacts that can result from even small releases to the environment from long lived radionuclides.

The environmental impact assessment is required for all waste management facilities, however, for facilities handling only short lived and low level waste the assessment can be done in a very simplified manner while for long lived waste, great concern must be taken to the potential long term impact due to build up of radionuclides in the environment.

Radioactive waste management activities may also result in non-radiological environmental impacts, such as chemical pollution or alteration of natural habitats. These impacts need to be carefully considered.

4.2. INFORMATION ON THE MANAGEMENT SYSTEM

The applicant is required to establish an integrated Management System to provide a single framework of the arrangements and processes to address all the goals of the organization. These goals include safety, health, environment, security, quality and economics plus other

considerations such as social responsibility. “The management system integrates all elements of an organization into one coherent system to enable all of the organization’s objectives to be achieved. These elements include the structure, resources and processes. Personnel, equipment and organizational culture as well as the documented policies and processes are parts of the management system. The organization’s processes have to address the totality of the requirements on the organization as established in, for example, IAEA safety standards and other international codes and standards” [15]. The requirements for the entire Management System are set up in the IAEA Safety Standards Series No. GS-R-3 [15] and only briefly mentioned here.

The applicant is required to provide documents and information on the Management System of its organization. The Management System should cover all waste management activities to be carried out, irrespective of whether they are individual or composite activities. The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:

- the significance and complexity of each product or activity;
- the hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity;
- the possible consequences if a product fails or an activity is carried out incorrectly.

Generic guidance on Management Systems is provided in Ref. [17] and specific guidance on addressing the safety requirements in establishing Management Systems suitable for organizations that manage all types of radioactive waste is provided in Ref [18]. Its main features are as follows:

- The Management System should give assurance that the activity (e.g. clearance) or product (e.g. waste package) will conform to all applicable requirements, respecting the principle of carrying out the work correctly the first time. The Management System should include measures to be taken in the case that non-conforming waste packages are produced.
- Processes should be developed and controlled to ensure that conditions, limitations, or specifications related to the waste or activity are continuously met for as long as necessary. It may cost more to develop processes that will achieve this effectively, due to the additional design and development work required. It may also be more onerous to operate such processes. However, product quality will be more consistent, and overall costs and radiation doses may both be lower because of less need for remedial action (e.g. intrusive testing and rework, and the associated handling) to deal with product that does not meet specification.
- The Management System should include plans and arrangements for itself to continue for as long as is required to maintain continuous control of the overall waste management programme (liability), and to cover all stages of waste management from waste generation to disposal.
- The Management System should also be designed to allow future accommodation of technological advances that could have an impact on the waste management programme.

4.3. INFORMATION ON THE SAFETY ACTIVITIES OF THE OPERATOR

Information on other plans and programmes that are established by the operator in support of its safety activities should also be submitted to the regulatory body for review and assessment [14]. This includes areas such as:

– radiation protection;
– environmental monitoring;
– emergency preparedness;
– physical protection and security;
– fire protection;
– future decommissioning;
– public involvement.

4.3.1. Radiation protection

The management of radioactive waste is part of the entire ‘practice’ giving rise to the waste in the context of the recommendations of the International Commission on Radiological Protection (ICRP) [19]. National radiation protection requirements shall be established with due regard for the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [12]. In particular, the radiation protection of any persons who are exposed as a result of activities in management of radioactive waste shall be optimized, with due regard to dose constraints, and the exposures of individuals kept within specified dose limits.

The dose limits for normal exposure of workers and members of the public shall be applied as prescribed in national regulations. Internationally endorsed values for these limits are contained in Schedule II of the BSS.

In addition to provision for protection against the normal exposures referred to in the preceding paragraphs, provision shall be made for protection against potential exposures. A potential exposure is one that is not expected to be delivered with certainty but that may result from an unplanned event. Requirements for protection against potential exposures are also established in the BSS. They include managerial and technical measures to prevent the occurrence of incidents or accidents and provisions for mitigating their consequences should they occur.

4.3.2. Environmental monitoring

Requirements for environmental radiation monitoring associated with the management of radioactive waste shall be established by the national regulatory body, taking into consideration all potential releases into the environment that may occur. The general requirements together with guidance on environmental management systems are provided in Ref. [20].

4.3.3. Emergency preparedness

The applicant is required to prepare an on-site emergency preparedness plan and, depending on the legislation of the Member State, together with the competent public authorities, an off-site emergency plan.

These plans are needed to demonstrate to the regulatory body that the operator has undertaken appropriate planning for potential unplanned events. The emergency preparedness plans should clearly show the actions to be taken in potential accidental situations and these accidental situations should be described. The degree of complexity of the plans should be commensurate with the perceived risk. Basic requirements for emergency preparedness and response are set forth in Ref. [21].

4.3.4. Physical protection and security

Physical protection and security measures are required at waste management facilities to prevent the unauthorized access of individuals to areas for waste processing and storage and unauthorized removal of radioactive materials. The physical protection and security of radioactive waste and associated facilities require that both safety and security are approached in an integrated manner.

Information about the physical protection and security measures at waste management facilities is needed in order to demonstrate that appropriate methods have been adopted to protect the facility and its material. The possible threats to a predisposal radioactive waste management facility could be the sabotage by individuals having entered to the waste management facility without authorization and unauthorized removal of radioactive material from the facility.

An act of sabotage against the facility could create hazards to the personnel and a potential radioactive hazard to the public and environment. Radiological hazards are strongly dependent on the threat to be considered, on the type of radioactive material available in the facility, its inventory and the design of the facility.

Theft of radioactive material from the facility can also lead to high radiological hazards to the persons involved in this act, to the public and the environment.

Fundamental principles for physical protection and security are set by the Convention on the Physical Protection of Nuclear Material [22] (which are generally applicable to radioactive materials and radioactive waste), and the particular requirements for the physical protection and security of radioactive waste are defined in Ref. [23].

4.3.5. Fire protection

The applicant should demonstrate that structures, systems and components important to safety have been designed and located so as to minimize, consistent with other safety requirements, the probabilities and effects of fires and explosions caused by external and internal events.

4.3.6. Decommissioning strategy

The applicant is required to provide a preliminary decommissioning plan for the waste management facility [3]. The purpose is twofold: to demonstrate that all necessary measures were foreseen in design and operation of the facility to facilitate its future decommissioning, and that the facility could be decommissioned safely. A decommissioning plan should include proposals for the management of radioactive waste to be generated during decommissioning.

4.3.7. Public involvement

It is widely recognized that involvement of the public and ensuring transparency are the activities that must be included in a radioactive waste management programme to make it successful. Public attitudes, concerns, and expectations about the safety of radioactive waste management activities and facilities (e.g. concern about consequences of extended discharges, trust that long term organizational arrangements will be adequate, and the ability to respond to problems that may arise) must be considered.

Member States conduct public outreach programmes to facilitate public understanding and to build public confidence by various means (e.g. distributing materials, establishing exhibition and explanatory facilities, arranging visits to nuclear facilities and meetings with programme staff). There are two basic approaches to this issue. Public involvement can be conducted as a

part of the process of preparing an environmental impact assessment or the public is requested to participate in the authorization process at several different steps in the programme as specified in legislation.

In countries where there is a great concern over the back end of the use of radioactive material the authorization process has become more and more important. However, public involvement in the authorization process requires a national tradition in the field and should be used with great care. Countries not yet having significant experience of this should limit this part of the authorization process to information and communication. In any case, the applicant should indicate in his application what kind of public involvement is planned.

The following Sections (4.4–4.6) provide guidance to the licence applicants on the details of information and documents to be submitted to the regulatory body as part of the licence application and give advice on possible ways of obtaining this information and documents.

4.4. COLLECTION AND PREPARATION OF BASIC INFORMATION

4.4.1. Site characteristics

Most important information related to the site characteristics can be obtained from the following sources:

- Location of the site should be indicated by the relevant longitude and latitude on the maps obtained from authorized geographical organizations. Other maps should also be used or prepared showing the topography of the site and its neighbouring locations. Population density maps are normally prepared by governmental organizations for statistical purposes and can be used by the applicant. Population density should be evaluated in different distances from the facility in a circular form.
- Baseline measurements can be obtained by sampling from the locations in the site. The sampling should be done according to the relevant procedure set by the regulatory authorities. Environmental samples should be taken from the points which are more likely to be contaminated from regular discharges (gaseous, liquid). These points can be established in collaboration with the regulatory authorities, in order to avoid any further misunderstandings. Wind, groundwater and surface water directions should be taken into account.
- A description of the existing routes could be obtained from relevant governmental organizations but analysis of their adequacy for transportation of radioactive waste should be carried out by the applicant.
- Data on geology, meteorology, seismology, tectonics, hydrogeology and hydrology could be obtained from official information sources, on-site investigations and laboratory studies. If required data are not readily available it should be requested from the organizations concerned on a contractual basis or by other means.

4.4.2. Waste acceptance criteria

Definition of a waste characteristics and attributes, including performance data and identification of quality related parameters is necessary to provide assurance of conformance of received waste to the defined waste acceptance criteria. Clearly, radioactive waste or waste packages that do not comply with the waste acceptance criteria should not be accepted for processing/storage.

Waste acceptance criteria might be prepared in such a way that they either define the safety related envelope for the waste intended for handling, processing and storage or focus on specific requirements on individually characterized radioactive waste. Waste acceptance

criteria could be quantitative criteria or qualitative guidelines specified by the regulatory body that determine whether a waste is acceptable for a given waste management step.

The waste acceptance criteria for processing should include:

- a description of the origin of radioactive waste;
- physical/chemical/biological forms, amounts, radionuclide content and activity (on an annual basis) from each waste generator and a summary of all waste expected to be processed (on an annual basis);
- an estimation of the total amount and the activity of radioactive waste to be processed during the lifetime of the facility;
- an estimation of expected specific activity (for solid waste) and activity concentration (for liquid waste) before and after processing;
- a description of containers in which waste should be transported to the processing facility;
- a description of the system (database), which will contain the relevant inventory information (including waste package identification data) and steps taken to ensure that it is adequately maintained[2];
- details of generated gaseous, liquid and solid secondary waste.

The development of acceptance criteria for radioactive waste disposal might be performed in the following three stages:

(1) First, generic requirements are defined (a) on the basis of the national radioactive waste disposal policy; (b) on general information on the types and quantities of waste expected to be generated; and (c) on the availability of potential sites.
(2) Site selection and site characterization follow to determine the characteristics of the disposal site.
(3) Finally, specific waste acceptance criteria are established.

In the absence of a particular disposal site only generic waste acceptance criteria could be developed and those should be taken into account by the operator of the storage facility while developing his own criteria for storage.

Waste acceptance criteria for storage might first describe the general storage related aspects and criteria for the waste packages and then develop more specific requirements on the waste forms and the waste containers or vice versa. General quantitative acceptance criteria for waste packages consigned to a storage facility usually include:

- radionuclide inventory;
- limiting dose rate at the surface and a distance of 1 m from the surface;
- limiting surface contamination;
- mechanical integrity requirements (mechanical resistance of the packages to be stacked; no loss of integrity after a test drop from a defined height);
- satisfactory corrosion resistance of the package metal;
- limiting gas generation;
- sufficient thermal resistance;
- limiting or avoiding free liquids, explosive and pyrophoric materials, compressed gases, toxic and corrosive materials;
- maximum allowable weight per package and physical dimensions;
- unique identification;
- compliance with codes, standards and national regulations.

[2] The IAEA has developed a computerized database that is free to be used by its Member States.

These requirements have been presented and discussed in Ref. [36]. In many countries specific quantitative limits are applied to some or all of the above criteria. These criteria or limits are set to ensure that waste packages will still be in an acceptable physical condition for their safe retrieval and handling when they are moved to the next step in the waste management scheme (e.g. from storage to disposal). Some limits, such as the radiation dose rate, are mainly of concern for immediate handling (since the dose rate will be reduced over time), while others have a longer term impact, such as gas generation that may result in a fire or explosion years in the future.

4.4.3. Waste package specifications

Waste package specifications consist of a quantitative description of waste packages prepared for storage/disposal (see Section 4.1.3). It is important that all parties involved in the development, approval and implementation of the waste package specifications are consulted at the earliest opportunity. This will allow a cross-fertilization of ideas and promote smooth progress during the development, approval and implementation phases. It will, in particular, allow those involved to understand and reach a consensus on what can reasonably be expected within the specifications and on what can actually be provided.

Depending on the national legislation, a formal statement on the approval and acceptance of waste package specifications should be done by the regulatory body and in agreement with the operator of the storage/disposal facility. In the case of waste package specifications dealing with waste to be returned from foreign countries, official statements between the authorities of those countries are to be exchanged.

In compliance with a given regulatory context, contractual negotiations on waste processing and waste storage/disposal provide an ideal opportunity to clarify waste acceptance criteria and to define waste package specifications that must be followed. Important contractual relationships will exist between the waste generator and conditioner on the one side and the operator of the storage facility or repository on the other side, even if such a repository is not yet available. Close consultation between the waste generator and the storage/disposal operator will help take account of any aspects of the waste that are not the concern of the generators when they operate their facilities.

As with any interactive project, the preparation, approval and implementation of waste package specifications require careful definition of the task, realistic programming and appropriate allocation of resources to ensure efficient progress. This will allow cost benefits to be realized, especially through avoidance of backfitting, (both of equipment and control measures) to comply with requirements that existed but were earlier ignored. Waste package specifications must be reviewed regularly and updated as required (in accordance with the quality assurance system) to ensure that they continue to define the characteristics of the waste package. New versions of waste package specifications must be issued when significant changes to the requirements have occurred. It is imperative that waste package records reflect the waste package specifications in place at the time of package design and construction, including any subsequent modifications or upgrades.

The development of waste package specifications is a highly interactive process involving several disciplines and organizations, with regulatory requirements being the key component for developing effective package specifications [44]. For each stage of package design and construction, any contractual constraints must be taken into account. It is important to note that the waste package specifications must not be too prescriptive but concentrate on the main requirements.

The waste generator is the first to be involved, in order to characterize the raw waste and identify options for conditioning of the waste. At this point consultation with experts will be required to extract the results of technical assessments and the relevant R&D work. Additional R&D may need to be carried out, and the design of the conditioning process, control system, measurement system and the container may need to be modified. Conditioning plant designers need to be consulted early in order to avoid expensive backfitting in the future.

Consultation with experts is an acknowledged methodology to reduce uncertainty and confer added confidence. Confidence in the validity of results depends to a great extent on the outcome of the expert review process. Therefore, it is reasonable that evaluation activities and results relevant to the development of waste package specifications are subject to an expert review process. Evaluation results should be published so that they become available for detailed scrutiny by other experts active in the field.

Adopting the expert review process for developing waste package specifications may include forms other than the typical expert review of scientific publications. National radioactive waste management programmes normally have provisions for technical review of important activities. In some cases, the waste generator or conditioner may be required to organize critical reviews by independent bodies. Such reviews can additionally make use of the expertise of various specialists and can be effective in raising the level of confidence in the results of technical assessments and the R&D work. While it is possible for local experts involved in the national radioactive waste management and radioactive source control programmes to do this, experience has shown that it is very helpful if external experts are involved, because a broader expertise is obtained, and blind spots are identified better. Also, while developing waste package specifications, account should be taken of the world's best practices in this area in relation to both technology and radiation and nuclear safety. Issues of transport modelling and technologies to evaluate characteristics of radioactive waste are essential components to developing waste acceptance criteria and waste package specifications have reached a high level of complexity. In order to ensure consistency with best practices internationally, external expertise could be of great value, especially to developing countries.

When the waste form and package concept have been decided upon, all relevant parameters should be quantified in terms of ranges that may be achieved in producing the waste package. Maximum values for each parameter and factors of safety can then be determined. Such upper limits must then be compared with quantitative requirements and reconciled either by additional constraints on the waste package content or, if possible, by relaxing the requirements. The process may require modelling of the waste production process. If a number of waste streams are combined prior to conditioning, this also should be modelled.

The specifications may be split into a number of sections. A suitable structure would cover the following items:

- general introduction;
- waste container and associated items;
- waste composition and inactive feed materials;
- formulation envelope, process description and conditions;
- guaranteed parameters of the conditioning process;
- summary of the supporting R&D, identifying parameters that show the waste package is consistent with waste acceptance criteria;
- QA and QC arrangements;
- additional or supplementary information;

– figures and diagrams.

Each of these items should be developed interactively to ensure consistency. As in many other areas of the nuclear industry, experience has shown that many drafts may be needed before a formal version of the specifications is ready for issue.

4.4.4. Collection of information on the waste

The applicant should ask the regulatory body to provide a list of all potential waste suppliers and based on that briefly describe the activities at the user's premises that lead to the generation of radioactive waste. The radioactive waste of concern is usually generated from hospitals, research laboratories, industry, nuclear research reactors and facilities for radioisotope production. The applicant should establish a contact with the waste generators and obtain from him as much information on waste characteristics generated or to be generated by him as possible. Some characteristics of radioactive waste could be determined by knowing the radionuclides used in the application and the character of the use. That 'process knowledge' may be used in conjunction with sampling and analysis to determine waste characteristics. In some cases R&D will be required to ensure the feasibility of the selected method and its accuracy.

Specific steps or actions could be involved in the collection of data for historic waste to be retrieved from old storage/disposal facilities for processing in accordance with modern requirements. Methods used to retrieve old waste inventory data during administrative searches can be broadly grouped into searches for records, studies and interviews [24].

Record searches and studies represent both the main step and the principal tool of data gathering during an administrative search. This involves the searching of hard copies and electronic records. Initially, data retrieval may start as a targeted search, aimed at a particular piece of information, which may expand into more broad-based records search. Interviews may include talks with individuals in person, telephone calls, e-mails and fax messages as well as the use of standardized questionnaires.

The next step involves listing the potentially useful targets of the information search. These targets may include documents and records, institutions and persons. A list of places for search may include the following:

– governmental (state) authorities;
– non-governmental and international organizations;
– waste generators;
– users and owners of radioactive materials;
– manufacturers and suppliers of radioactive materials;
– transportation organizations;
– individuals and organizations involved in the management of radioactive materials.

For a number of reasons, the task of retrieval and verification of the old waste inventory records for some facilities, using administrative methods, may not be feasible, or the outcome of data retrieval is not satisfactory or unreliable. In such cases, it will be necessary to physically retrieve the waste from the repository/storage facility for subsequent characterization to arrive at a reliable and complete record of the waste inventory. The following methods can be used for characterization of the waste:

– visual observations;
– weighing: digital or analogue scales;
– radiation field survey;

– radiological contamination survey;
– radiographic and tomographic examination;
– activity measurement;
– container integrity survey;
– destructive testing.

Selection of appropriate methodology requires careful planning and preparatory work, including segregation and collection of the retrieved waste. More detailed guidance on the selection and implementation of various characterization methods for the waste retrieved from old storage and disposal facilities is provided in Ref. [24].

4.4.5. Description of the facility, its systems and components

The description of the facility, its systems and components is available from the designer of the waste management facility, designers or suppliers of systems and equipment as well as the designers of associated support facilities and sub-systems.

The following should be described and explained in the description of the facility:

– The purpose and primary functions of the parent system and sub-systems, component or part (hereafter called component) and how they operate to achieve the main function of the parent system.
– Subject component boundaries and requirements on interfacing parent system components or other systems.
– Measures for optimizing construction, manufacturing, fabrication and installation methods, the construction schedule, and for working in potentially radioactive areas.
– All design limits and strength requirements such as design pressure and temperature and transients and any load combinations.
– The design constraints on the component imposed by maximum/minimum levels, regulations, previous operating history and configuration.
– Environment in which component is to operate in, including hazards from other systems/components.
– Reliability of component in terms of minimum acceptable limits of production and nuclear safety. Reliability may be achieved by, but not limited to: providing redundancy, periodic testing, physical separation, built-in test and self-test features and fail safe design for preventing common mode failures and human errors.
– Major sub-components to be maintained and maintenance facilities, special equipment, tools, access, lay-out, services, modularization and standardization.
– Major sub-components to be inspected during the inaugural and at mandatory intervals during the component’s life cycle.
– Measures pertaining to public, personnel and environmental safety from nuclear and conventional health and safety hazards and hazardous materials.
– Fire detection and fire prevention measures.
– Physical protection and security measures.
– All the regulations, codes and standards including the specific clauses, issuing organization, document number and year of issue that followed in design.

4.4.6. Applicable regulatory documents

It is necessary for the applicant to identify the national legislation, standards and regulations applicable to given waste management processes and activities and products resulting there from operation of the particular waste management facility and to demonstrate that they will

be fulfilled. This includes all requirements for radiation protection, safety, waste management and waste acceptance. These documents will guide the applicant in the establishment of an appropriate Management System and designing suitable processes to obtain desired results. It should also identify relevant areas of the national policy, if it exists.

In the case where there is no national legislation or when the national legislation is incomplete, IAEA Safety Standards and accepted good international practices can be useful for the applicant when selecting requirements for the waste management processes.

4.4.7. Modes of operation

As a minimum requirement, the predisposal waste management facility shall be operated according to the manufacturer's instructions and recommendations, provided that they are within the authorized operating limits and conditions. A list of operational requirements shall be prepared before or during the design phase. The requirements should be considered in the design of the facility to the extent practical. The following are a few examples of possible operational requirements:

- operational limits and conditions;
- monitoring, testing and inspection;
- local and remote controls for important components;
- visual contact between control room and main working area(s);
- access to rooms and work levels without unnecessary detours.

Maintaining normal operating conditions is an essential requirement for the operation of a predisposal waste management facility. Therefore, the design shall provide either intrinsic compliance with such a requirement, or effective means for monitoring the process and preventing unfavourable conditions from arising. The latter includes control of the input waste quantity and quality, and demands careful monitoring of the process parameters.

The facility shall be provided with sufficient controls for a system shutdown, and for returning the system to a stable condition from all situations that can occur with any significant probability.

The design of the facility should include provisions to facilitate component replacement, adjustment and proper servicing. Many components may not need to have the full lifetime planned for the entire system.

4.4.8. Demonstration of safety

The applicant should demonstrate that the performance objectives of the waste management facility and the processes that are used can be satisfied and that the overall system is acceptable for licensing or authorization (Ref. [3], para. 5.3). This demonstration is carried out by performing safety assessment. The results of the safety assessment should include the predicted impacts on the workers, the public and the environment.

Safety assessment requires the development of both qualitative and quantitative arguments depending on the waste characteristics, nature of processes used in the facility, design data, and neighbouring environment. The results of safety assessment are presented in the safety report that shall be submitted to the regulatory body.

It should also identify all operating conditions that might result in abnormal situations but which still are within the design basis for the facility and thus should not result in unacceptable safety situations. The information should be detailed enough to allow the regulatory body to assess the completeness of the limiting risks/scenarios. The safety

documentation demonstrating the acceptability of the situation as compared with national regulations or good international practice should be included.

The extent of the safety assessment depends on the propensity for risk (the severity of harm that may be caused by the hazard and the likelihood of harm) to the workforce, the public and the environment from the proposed operations. A simplified assessment approach should be adequate for the majority of small users and operators. An example of a fault schedule for such an assessment is given in Appendix II of Ref [25]. The purpose of the fault schedule is to identify hazards to operators and to propose engineered, administrative and contingency controls to result in acceptable risks.

For simpler and smaller operations the integrated waste management system may be fairly straightforward and can be covered in brief. The focus of safety assessment for users and operators managing small quantities of waste should be on demonstrating compliance with regulatory requirements. An example of the safety report for a simple waste storage facility is provided in Appendix 1.

Work has been underway within the IAEA for a number of years to develop a Safety Guide addressing safety assessment for facilities and activities associated with the management of radioactive waste prior to disposal. This process has led to the realisation that the approach to such safety assessment is very similar in nature to that required for many other nuclear fuel cycle facilities and for facilities that handle radioactive materials or make use of radiation sources. As a result the draft Safety Guide on Safety Assessment for Nuclear and Radiation Facilities Other Than Reactors and Waste Repositories has been developed [26] to cover all these facilities. Whilst there are many similarities, there are also significant differences and the guide emphasises the importance of ensuring that the extent and complexity of the assessment is commensurate with the nature of the activity or facility and its attendant risk.

The ongoing international SADRWMS (Safety Assessment Driving Radioactive Waste Management Solutions) project deals with the examination of international approaches to safety assessment in aspects of predisposal radioactive waste management, including waste conditioning and storage. In comparing international approaches to safety assessment in these areas, it is anticipated that a body of safety assessment methodology will be developed which will be acknowledged as international best practice in these areas. The SADRWMS project will encompass all types of radioactive waste including disused sources, small volumes, operational waste and spent fuel, legacy and decommissioning waste, and large volume NORM residues [27].

While not exhaustive, the following section outlines the content of a safety assessment report.

4.4.9. Contents of a safety assessment report

4.4.9.1. Assessment context

Assessment purpose

The general purpose of the predisposal waste management facility safety assessment is to determine the radiological significance of normal operational practices, potential future discharges of radionuclides and abnormal conditions. To a large degree the purpose of the assessment will define the amount and type of documentation that should accompany the assessment. The assessment will only consider radiological impacts; for example, chemical or biological toxicity will not be assessed (It is recognized that this issue may be important, but it is assumed that it will be dealt with in a separate safety case aimed at compliance with different environmental regulations).

Assessment criteria

Safety criteria should be mentioned clearly in the beginning of the report. The assessment can be based on national regulations (if they exist) or on broadly accepted international principles (e.g. ICRP 60 [19], IAEA Fundamental Safety Principles [1]). These criteria are the assessment endpoints; hence the individual effective dose will be calculated to demonstrate progress towards compliance with regulatory requirements.

Assessment philosophy

Although the nature of the endpoint may have been defined clearly, it is also necessary to make clear the nature of assumptions used in assessment of the endpoint. Exposure group assumptions are an important example but it is clear that the problems with adopting a consistent approach to the level of pessimism can arise in any part of the assessment. A statement setting out **the approach to be taken should be included in the assessment context.**

Waste acceptance criteria

Characteristics of radioactive waste important for safety should be clearly defined in the waste acceptance criteria either for the processing or storage facility. The waste characteristics together with the process description are the basics for safety assessment.

Process description

All the processes and activities that are going to be performed in the facility should be described and explained. The description should include clearly the safety measures taken in each activity. The process description is normally provided as the basic information for the facility under authorization (see Section 4.1.3).

Site characterization

The site characterization should identify in general terms the current surface topography and climate in the vicinity of the site. The characteristics of the site required as part of the safety assessment are the same as needed for providing the basic information by the applicant (see Section 4.1.1). A clear distinction should be made between information that is verifiable and the assumptions made for assessment purposes. The site context may help to define the spatial domain to be included within the biosphere system description.

Geosphere/biosphere interface

The structure and modelling requirements of the biosphere model will depend on the radionuclides under consideration and the interfaces assumed between the geosphere and the biosphere. A clear definition of the interface, and recognition of where in the assessment particular processes are being taken account of, is necessary to ensure that all relevant processes are included.

4.4.9.2. Scenario generations and justification

The purpose of scenario use in the safety assessment of a radioactive waste management system is to address to uncertainties associated with the human behaviour, separate consideration of different normal and abnormal operational situations, evolution of the system in future and data uncertainties. Examples of the scenario generation and justification as applicable to waste disposal are provided in Ref. [28]. The approach selected is also relevant to predisposal waste management and it depends on various factors such as the assessment purpose, the level of information available, and the regulatory framework.

Generally a scenario can be considered as a hypothetical sequence of features, events, and processes (FEP) leading to human exposure. The objective of scenario development is to establish the framework for calculation of radiological consequences when making specific safety assessment for a specific object. In this regard it is very helpful to follow general assumption fixed in the assessment content and focus efforts on the aspects most relevant to the purposes of assessment and in particular on the licensing requirements (this helps to reduce the set of scenarios to the manageable number). The final set of scenarios to be considered within the safety assessment is intended to take into account the uncertainties related to the system components, different combinations of FEP which have the potential of impairing the capabilities of the treatment facility to confine the waste.

Scenarios depend on the environment, waste processing operations and system characteristics, on events and processes that could initiate release of radionuclides or influence their fate and transport in the environment, but moreover the list of scenarios depends on the assessment purposes.

In assessment of predisposal waste management facilities all possible scenarios could be divided into two big groups:

(a) assessing the safety for the operational staff;
(b) assessing the safety for the public and the environment.

The first group scenarios should cover both normal and abnormal conditions. For normal operations exposure of the operational staff is mainly formed by external irradiation from pre-treated waste, treated waste and waste packages during their handling, transfer and storage.

Analysis of the operations leads to the generation of possible unexpected events that can result to the exposure of operational personnel during operations. Due to outlying location of the public the second group of scenarios can be subdivided into number subgroups according to the possible transport mechanisms: water, air, soil dust, and initiating events from normal and abnormal conditions.

In this stage the analyst will:

- review and screen the FEPs;
- generate scenarios with selected FEPs;
- select the most relevant and the worst case scenarios.

4.4.9.3. Development and selection of scenarios

The associated scenarios should be screened in order to provide a set of scenarios such as gas release, drop and crush, fire, tipping accident, direct irradiation, liquid release and solid release. Gas release must be considered under normal operation condition for both primary and conditioned waste in the facility. Gas release will depend on the inventory, properties of the waste and leak tightness of the waste package, and the design of the facility.

The drop and crush of waste packages is possible during the operation of the facility; it corresponds to an abnormal situation. Exposure to workers will be principally due to direct irradiation. The dilution volume is important for assessing the radiation dose which might be caused by inhalation. If the facility is operated in open air, the contribution of inhalation will be low but might need to be assessed.

The crash of the flying objects cannot be completely dismissed. However to derive activity limits from these events for either the waste or waste packages is judged to be inappropriate when the likelihood of such events and the wider consequences are considered.

Exposure due to direct irradiation of workers is usually kept to acceptable limits by restricting the dose rate in the case of a waste processing facility. Generally, processing of waste in a facility provides a higher risk of exposure by direct irradiation even under normal operation conditions.

For unconditioned waste tipped into facility, solid dust release can be assumed to occur in the associated scenario. External irradiation and inhalation need to be considered for workers.

Fire can be excluded for conditioned waste during unloading operation in storage with regard to operational conditions and to appropriate intervention procedures. Nevertheless, for unconditioned waste, fire must be considered in case of spontaneous ignition of the waste.

In light of developed scenarios, it will be possible to propose a limited and justified set of operational scenarios to be taken into account as a basic for deriving the exposure of staff and the public.

4.4.9.4. Model development

One of the ways to move from scenarios to mathematical models is the use of conceptual models. This can be done by setting tables, layouts and block diagrams showing the scenario schematically. At this stage all conceptual models should be prepared and processes expressed mathematically.

Mathematical representation of a conceptual model depends on a proper understanding of the importance of risks and scenarios to radiological assessment and the ways in which they can best be interpreted mathematically, given available scientific information. Modelling constraints, such as the preferred solution method for the model, or the availability of data, may restrict the ability to represent particular effects or processes. Moreover, the process of reviewing data sources and references to identify or select suitable parameter values for the model may result in modifications to the model [28].

Several computer codes could be developed on the basis of mathematical representation of conceptual model for the purpose of the assessment of a predisposal facility. Only verified and validated computer codes should be used. The validation of a computer code is not an easy task for developing Member States planning a first predisposal waste management facility. This can be solved by using the computer codes which has been used for licensing by other Member States instead of developing new codes.

4.4.9.5. Presentation and assessment of results

The safety assessment results in a body of all relevant information that is important for understanding and acceptance of the facility operation. These results will be used for various purposes. In the licensing process they are used principally for comparison with regulatory requirements applicable to predisposal waste management facilities [3].

An example of the safety assessment of the simple facility constructed for storage of disused sealed radioactive sources is given as Appendix 1.

4.4.10. Environmental protection considerations

An Environmental Impact Assessment (EIA) is an important tool for incorporating environmental concerns at the project level. The EIA should be carried out as early as the project planning stage as part of the feasibility study thus it can assure that the facility will be environmentally feasible. The general objectives of the EIA are to provide:

(a) baseline information about the environmental, social, and economic conditions in the facility area;

(b) information on potential impacts of the facility and the characteristic of the impacts, magnitude, distribution, critical groups, and impact duration;
(c) information on potential mitigation measures to minimize the impact including mitigation costs;
(d) an assessment of an alternative project in terms of financial, social, and environmental impact. In addition to the alternative location of the facility, the facility design or facility management may also be considered.

The standard EIA report format addresses such issues as exploration of various alternatives, evidence of public consultation and social acceptability, economic analysis of impacts, and direct and indirect impacts. The suggested outline of the EIA report is given below.

4.4.11. Contents of an environmental impact assessment report

4.4.11.1. Introduction

This section usually includes the following:

- Purpose of the report, including (a) identification of the facility and its proponent, (b) brief description of the nature, size, and location of the facility and its importance to the country, and (c) any other pertinent background information.
- Extent of the EIA study, including the scope of the study, magnitude of effort, and persons/expertise or agency performing the study and corresponding person months.
- Brief outline of the contents of the report, including any special techniques or methods used for identifying issues, assessing impacts, and designing environmental protection measures.

4.4.11.2. Description of the facility

The facility should be described in terms of its basic activities, location, layout, and schedule (in terms of the project cycle). Information required for the description of the waste management facility is actually the same as to be presented as the basic information (see Section 4.1.3).

4.4.11.3. Anticipated waste

The anticipated waste should be described in terms of physical, chemical, radiological characteristics as defined in waste acceptance criteria or waste package specifications.

4.4.11.4. Description of the environment

This section should contain a description of the area to provide a clear picture of the existing environmental resources and values within which the impacts must be considered. Detailed methodology to gather information, including data sources, should also be briefly described. As much as possible, the baseline environmental information should be presented in maps, figures, and tables. Information required for the description of the site environment is given in Section 4.1.1.

4.4.11.5. Alternatives

The consideration of alternatives (including ‘zero’ option) is one of the more proactive sides of environmental assessment — enhancing the facility design through examining options instead of only focusing on the more defensive task of reducing adverse impacts of a single design. This calls for the systematic comparison of feasible alternatives for the proposed facility site, technology, and operational alternatives. Alternatives should be compared in terms of their potential environmental impacts, capital and recurrent costs, suitability under local conditions, and institutional, training and monitoring requirements.

4.4.11.6. Anticipated environmental impacts and mitigation measures

Review of characteristics of each environmental impact

This section is the key presentation in the report and if it is not sufficiently comprehensive it may lead to the delay of facility operation. It is necessary to present a reasonably complete picture of both the human use and quality of life gains to result from the facility due to the utilization, alteration, and impairment of the natural resources affected by the facility, so that fair evaluation of the net worth of the facility could be made [29].

This section will evaluate the expected facility impacts (in as quantified terms as possible) on each resource or value, and applicable environmental guidelines wherever any significant impact is expected (including environmental risk assessment, where appropriate). Environmental impacts to be investigated will include those due to:

(a) facility location;
(b) possible accidents;
(c) design;
(d) construction, commissioning, regular operations, upgrading and decommissioning.

Where adverse effects are indicated, measures for minimizing and/or offsetting these, and opportunities for enhancing natural environmental values should be explored. Both direct and indirect effects should be considered, and the region of influence indicated.

Mitigating adverse effects

For each significant adverse environmental impact, the report should carefully explain how the facility design minimizes the adverse effects and in addition how the facility design, to the extent feasible, includes provision for offsetting or compensating of adverse effects and for positive enhancement of benefits or environmental quality. Where substantial cost of mitigation measures is involved, alternative measures and costs should be explored.

Irreversible and irretrievable impacts

The report should identify the extent to which the proposed facility would irreversibly curtail the potential uses of the environment. Other impacts that may be irreversible include alteration of historic sites, and expenditure of construction materials and fuels. Also, projects through estuaries, marshes, etc., may permanently impair the area's natural ecology.

4.4.11.7. Economic assessment

This section may be drawn from the economic analysis conducted as part of the facility feasibility study. It should include the following elements to be integrated into the overall economic analysis of the facility:

- costs and benefits of environmental impacts;
- costs, benefits, and cost-effectiveness of mitigation measures.

4.4.11.8. Environmental management plan

The environmental management plan should describe which and how mitigation and other measures will be implemented to enhance the environmental protection. It should explain how the measures will be managed. The following issues should be described in the plan:

(a) introduction of mitigation measures by design;
(b) implementation of mitigation measures by contractors;
(c) social development programme (e.g. resettlement plan);
(d) contingency plan for natural or other disasters, and facility contingencies; and

(e) environmental management and monitoring costs including mitigation costs.

4.4.11.9. Conclusions

The report should present the conclusions of the study including:

(a) benefits which justify facility implementation;
(b) explanation of how adverse effects could be minimized, offset and/or compensated to make these impacts tolerable;
(c) provisions for follow-up surveillance and monitoring.

It is very difficult for some developing Member States to collect the detailed environmental information in a short period. It is recommended that the operator will draft the environmental management plan to collect these data as early as possible and consult with the regulatory body about this plan prior to carrying out environmental studies.

4.5. MANAGEMENT SYSTEM

The Management System should be described by a set of documents that establish the overall controls and measures to be developed and applied by an organization to achieve its goals. The documentation on the Management System to be submitted to the regulatory body together with the licence application should include the following [15]:

- the policy statements of the organization;
- a description of the Management System;
- the organizational structure;
- definition of the functional responsibilities, accountabilities, levels of authority and interfaces for those managing, performing and assessing work;
- the processes and supporting information that describes how work is to be carried out and recorded.

Many issues may be sufficiently important to warrant consideration when developing the Management System for radioactive waste management, such as:

- national policy for radioactive waste management;
- legal aspects of some waste management activities (such as state or provincial regulation of discharges from treatment facilities, occupational health regulations, hazardous material regulations, mining regulations);
- restrictions on the transportation of radioactive and hazardous materials across local jurisdictional boundaries;
- physical protection and security provisions that may be required, as appropriate, in order to protect nuclear and other radioactive materials;
- operational limitations derived from agreements with local authorities or organizations, operating logistics or other sources;
- needs, expectations and concerns of the successive organizations managing the waste (e.g. about the adequacy of the activities performed by the organizations that carried out earlier steps, and the ability of the next organizations in the sequence to continue the work);
- public attitudes, concerns, and expectations about the safety of waste management activities in the long term (e.g. concern about the consequences of extended discharges, trust that long term organizational arrangements will be adequate, degree of confidence in the long term performance of waste storage facilities and the ability to respond to problems that may arise);

– other stakeholder concerns (e.g. cultural expectations about working hours and the composition of the workforce, social expectations about distributing risks and benefits, economic constraints if nuclear activities have a broad scope but are on a small scale, political choices about sustainable development activities).

A waste management facility could be part of the entire organization that had submitted the documentation on the integrated Management System to the regulatory body for authorization of its operational activities. In this case no separate description of the Management System is required. However, if a licence is required just for a predisposal waste management facility the documentation on the Management System of this particular facility should be prepared and presented to the regulator.

4.5.1. Responsibilities

Responsibility for the Management System should be established in the organization applying for an authorization. In deciding on the member of management who is responsible for the Management System for a waste management organization, top management should ensure that all the waste management activities are covered in a comprehensive and coherent manner, and are covered continuously over the period that the associated safety, health, environment, security, quality, and economic concerns continue.

Senior management should set the goals, define policies and requirements assign responsibilities and authorities, and provide for the performance and assessment of work. The Management System should identify all work delegated to external organizations, the lines of communication and the interfaces between internal and external organizations. The responsibility of each organization, as it relates to the assigned work, should also be described.

The Management System should be binding on all individuals.

4.5.2. Policy statement

The Management System for an organization should specify the requirement to create and periodically review the policy in the field of radioactive waste management and the related arrangements to do so. The waste management policy should cover safety, health, environmental, security, quality and economic aspects.

The statement on the waste management policy is to be developed by senior management. The policy statement needs to be appropriate to the activities and facilities of the organization. The policy statement should reflect the commitment of senior management to attaining their goals and objectives; their priorities; and, how continual improvement will be measured. Management at all levels shall demonstrate commitment to the establishment, implementation, assessment and continual improvement of the Management System.

4.5.3. Description of the Management System

The issues below should be considered as the basic formations in preparation of the Management System and should be covered in view of the complexity of the overall waste management infrastructure and capacity of the country.

– A description of methods to check the information on waste characteristics provided by the waste generators (e.g. audit, review of documentation or measurements) in order to get confidence that their data meet the required degree of accuracy.

- Interfacing with other involved organizations, including waste consignors, equipment and material suppliers and contractors.
- A description of methods to be used for process control.
- Information management systems, including those for document and record control. A record management system should include procedures for the preparation, collection, identification, classification, indexing, updating, archiving, restoring and retrieving of records as well as procedures for periodical review and auditing.
- A system for the records of staff with their trainings and experience, particularly those who have responsibility for any operations, which may involve safety.
- Proposals for continuous improvement of the system, which include periodic external and internal audit, self-assessment, and management review. This involves critical evaluation of the non-conformances and corrective actions, assessments and feedback and making consequential improvements to the Management System.
- A knowledge management programme.

The guidance for designing a Management System can be found in Ref. [18]. The requirements for the processes for treating, handling and storing radioactive waste are introduced in Refs [15, 30-32]. For example, in ISO 17025 [31] the administrative and technical steps are presented that should be followed to perform tests in order to obtain qualified and good products.

4.5.4. Grading the application of Management System requirements

The applicant could identify the relative importance of the various activities, facilities, equipment, and waste products to meeting overall safety, health, environmental, security, quality and economic requirements, with safety and environmental protection being of primary importance. Resources can then be selectively allocated and processes selectively designed to control the activities, facilities, equipment and waste products adequately, effectively and efficiently. Controls will vary for different facilities and activities.

The applicant should not use grading as a justification for not applying all of the necessary Management System elements or required quality controls, or for performing less than adequate technical assessments of items that are less evidently important to meeting safety, health, environment, security, quality, and economic requirements.

4.5.5. Organizational structure

The following information could be presented by the applicant on the organizational structure:

- An official name of the applicant and data regarding the administrative and juridical aspects.
- An address and contact details of the head office and other facilities operated by the applicant organization.
- A concise history of the applicant organization (two cases: a new licence or renewal of the licence), highlighting topics of interest to the application.
- Organizational arrangements with other governmental authorities (e.g. other regulatory authorities).
- A declaration (proof or commitment) of financial ability that may include insurance of civil liability of the applicant organization to fund both the proposed operations and also decommissioning of the site.

- An organizational structure, in particular showing the position of the staff involved in managing and operating the facility (covered by the application), including outsourced services.
- Responsibilities of the staff during operation, maintenance, incidents and accidents.
- A description of any committees or other bodies, which advise on radiation safety.

Most of the information and documents are available or easily obtainable but those need to be presented in a clear and precisely structured way. Ownership of the site should be demonstrated by legal documents issued by competent authorities. If the site is owned by other organizations or facilities, the applicant should submit a copy of the permission of the owner for operating life of the facility and till the end of decommissioning.

4.5.6. Provision of resources

Waste management activities will require resources in the areas of finance, human resources, and infrastructure and work environment. Arrangements to provide the resources for waste management activities should incorporate the demands imposed by the safety, health, environmental, security, quality and economic aspects associated with the full range of activities involved and the potentially long duration of the activities.

4.5.6.1. Cost and financial resources

Special attention should be paid to the estimation of the cost of radioactive waste management including decommissioning cost and ensuring their adequate funding. It may be difficult to make realistic estimates of costs for waste management activities that are still in the planning stage, and with which no experience has accumulated.

Project management controls available to the applicant follow accepted and proven methodologies widely used in the nuclear industry. The methodology involves dividing the project into phases establishing a detailed Work Breakdown Structure (WBS). The WBS concept was designed to help manage work systematically. For this methodology, the WBS should be used as a checklist to gather the applicable costs systematically in a standardized form. Project baselines are established for costs, schedule, occupational radiation exposure, waste generation and any other parameter appropriate to the project that is to be closely monitored. A Program Evaluation and Review Technique (PERT) can also be used to monitor the project evolution, with a variance analysis performed for each baseline. This methodology calls for forecasting the estimated costs at completion to compare against the projected budget.

A number of other analyses are useful for examining the cost estimates. The cost of an option may be sensitive to several cost drivers. For instance, hydraulic conductivity of soils, level of contamination, and regulatory limits are examples of cost drivers pertaining to waste processing technologies. A sensitivity analysis determines which cost drivers significantly impact the cost of an option. An uncertainty analysis allows the cost estimator to determine how much an estimated total cost may vary, given that elements of the total cost are uncertain. A cost-benefit analysis on the total life cycle costs of each proposed technique is performed to determine the potential cost reductions, and includes all direct labour, materials, equipment, primary and secondary waste generation and occupational exposure.

For any estimation of the waste processing/storage cost is absolutely necessary to quantify and characterize existing waste streams and waste anticipated from the operation of a waste generating facility during its lifetime.

A waste management facility needs to be designed, constructed and commissioned (pre-operational phase) followed by operation and finally decommissioning (post-operational

phase). If it is the case, for each waste stream it may be need to further elaborate WBS by including:

- all costs for investment, depreciation, operation, decommissioning, and manpower;
- parallel costs for the handling of secondary waste, for surveillance and monitoring;
- costs for additional research and development, demonstration and/or adaptation.

Furthermore, it might be needed to continue in more detailed WBS levels to arrive to basic elements to address the level of details required for the cost estimate. In any case, other (non-facility or process) costs including infrastructure needs such as roads, transport equipment, processing and storage (if outside the waste management facility) and disposal should be also estimated. Then, the next level of WBS should be economically assessed. Process life cycle costs are to be integrated into systems life cycle costs.

For successfully financing waste management activities in a developing country, it is essential for the government as well as the operator to make a thorough financial analysis for ensuring that there is enough resource to complete all the project components as well as to carry out all the planned activities. A funding scheme, which is connected to the financial analyses, should also be prepared covering the resources of waste management activities for the projected time period. Due to the local lows and/or preferences, funding may be provided from the state budget or fees from the waste generators or mixed. However, the ultimate responsibility for the radiation protection of the public, including radioactive waste management, resides as a governmental liability.

4.5.6.2. Human resources

The reliability and effectiveness of waste management activities depend on all personnel in all the organizations involved. At all times, they should carry out their assigned work competently and with a clear understanding of the consequences for safety and environmental protection of their tasks. For a new facility, a problem could be to prove the competence of the personnel. This can be solved by training the personnel before submitting the licence application (e.g. during the construction phase) or hiring outside experts in the beginning of operation. Training programmes, procedures and succession plans should be established by the licensee and demonstrated to the regulatory body that suitable proficiency is achieved and maintained and the potential loss of adequate knowledge, practical experience and technical expertise over time will be avoided.

A training programme is recommended for new staff and periodically to update knowledge of the existing staff (retraining). Subjects of training should include fundamental and practical aspects of waste management and radiation protection, regulatory requirements, waste characteristics and details of operational procedures relevant to their role in the management of radioactive waste. Management of the facility must ensure that all individuals understand the nature and hazards of the waste, all relevant operating procedures, associated safety procedures and the importance of quality control applied to each stage of the waste management programme.

The operator is advised to create a system for keeping records of all training and retraining activities. Refreshing training should be foreseen at appropriate intervals to reinforce the purpose of the quality control procedures and ensure employees have a thorough understanding of their role within the overall implementation of the waste management programme.

4.5.7. Infrastructure and work environment

The applicant should demonstrate that consideration is given to measures for ease of operation, equipment and system maintenance, and eventual decommissioning of the facility.

For long term waste management activities, future infrastructure requirements should be identified and plans should be made to ensure they will be met. Such planning should consider the continuing need for supporting services, spare parts for equipment that may no longer be manufactured, equipment upgrades to meet new regulations and make operational improvements, and the evolution and inevitable obsolescence of software.

Consideration should be given to the need to develop monitoring and measuring programmes and inspection techniques for use during extended periods of waste storage.

4.5.8. Process implementation

All the management and work processes needed to satisfy safety, health, environmental, security, quality and economic requirements associated with managing waste are required to be identified, developed, implemented, maintained and appropriately improved in a controlled fashion.

4.5.8.1. Process control

To ensure that the product resulting from a process has the required characteristics it is necessary to control process parameters, which have to be given within given ranges. Within a Management System it is necessary to monitor these parameters and record them also ensuring quality control of the values recorded. All deviations from the documented process procedure as well as other non-conformities should be documented together with the corrective actions. The process control records should make it possible to verify, at any time, how the process has been performed and thus make it possible to determine the characteristics of the product and consequently its quality [33, 34].

Intrinsic and desired properties that need to be quantified, monitored or otherwise assured have to be assessed for each management step. For handling, processing and storage operations, the requirements mainly concern the safety of operators. Security of the waste from interference or theft and behaviour of the waste packages under possible abnormal conditions need also to be considered. Quality of the outputs should not rely on exhaustively checking the final product at the time of discharge, disposal or transfer from the facility. Quality control checks should be completed at identified essential stages during processing to give assurance that it conforms to defined parameters.

Sampling and sample preparation required for process control should be done in accordance with approved procedures. For all parameters the uncertainty of measurement should be estimated and recorded.

4.5.8.2. Control of activity measurement/determination

One of the most important issues in radioactive waste management is the radionuclide inventory. The measurement/determination of radionuclides is therefore of greatest importance. However, this is in many cases a very difficult task. In some cases it is only possible to measure the activity content by taking samples and performing advanced sample preparation before measurements can be done in a laboratory. It may therefore in many cases be acceptable to exclude the presence of certain radionuclide by indirect methods like knowing the origin of the waste and what radionuclide has been handled at that place. The use of indirect methods such as key nuclide and correlation factors should always be used with

care. Further guidance on the radionuclide measurement for the characterization of radioactive waste can be found in Ref. [35].

4.5.8.3. Procurement control

Material and purchased items control to be used in processes need to comply with given criteria in order to ensure that the process will proceed smoothly. The limiting values of the important parameters should be known and assured that they are met. Attention should be paid that some of the materials are sensitive to storing conditions and storage time. For each material the critical verification steps have to be identified and documented.

For all equipment used in the processes or for control of specific parameters (e.g. dosimeters, spectrometers, pH-meters, spectrometers) there should be technical specifications ensuring that the equipment can do the task for which it is proposed. For all new equipment the conformity with the technical specifications should be demonstrated before taking the equipment into use. In some cases, the operator should ask the manufacturer or supplier to train the personnel in the use of equipment. Functional tests should be foreseen before equipment being used. Operating manuals should be available in a language fully understandable to the user of the equipment including recommended service, calibration and maintenance programme. For measuring equipment calibration need to be done and documented in accordance with established procedures. Attention should be paid to maintenance; the manufacturer should assure it during the lifetime of the equipment. Other cases are the equipments manufactured long time ago for which the manufacturer does not provide support anymore.

4.5.9. Control of documents

Documents as a list of equipment, information technology, industrial practices, language, educational levels and regulatory requirements evolve should be periodically reviewed and kept up to date.

4.5.10. Record keeping system

The preparation and maintenance of a comprehensive record keeping system is an essential component of the Management System. In many instances, local regulations govern the records that are required to be kept. In this case should keep records in compliance with those regulations. Records should be clear, legible and maintained up to date at all times, such that they are readily available during inspection [32, 37]. It is suggested that the record system be computerized and should be restricted to relevant data. Multiple copies of the records or access to the database by several regulatory bodies may be required. The Management System should detail the period of retention of records.

The documentation system should provide an integrated record of the waste from the time of generation through handling and treatment to storage and final disposal. The system must be able to identify and track any individual waste package. One way this can be achieved is by use of a bar coding system which can be read into a computer database. Records that provide evidence that activities affecting quality and safety have been performed according to specified requirements should be prepared according to documented quality control procedures. These records should subsequently be subject to a systematic audit as part of a quality assurance programme to demonstrate that the control systems are effective.

The record keeping system must provide for identification, collection, indexing, filing, storing, maintenance, retrieval and disposal of records, including provision for long term storage. Records must be stored and maintained in such a way that they are readily retrievable

in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Access to the record system or database must be allowed only to authorized individuals, and the system should be designed to resist tampering or alteration.

The system should provide appropriate back-up or redundancy to assure that data will not be lost due to unexpected accidents or events.

At least the following information should be included on the labels on individual waste packages:

- identification number;
- waste radionuclide inventory;
- surface dose rate;
- weight.

The exact format and level of detail required should be documented in the waste acceptance criteria of the waste management facility. The documentation system should also record the package number and its current status (e.g. storage location and treatment date). The information recorded enables the waste to be tracked, handled, processed, stored and disposed of safely.

4.5.11. Non-conformance, preventive and corrective actions

Even when a formal Management System is implemented there is a possibility of incidents and other reasons for non-conformance with the accepted/agreed values. For such situations there should be written procedures for actions to be taken, for example, when a dose rate above the accepted value is measured. Corrective actions to eliminate the cause of the non-conformance in order to prevent recurrence should be recorded once the actions have been taken and are completed.

Some waste packages may not be capable of meeting some or all of the identified waste acceptance criteria for storage. This can be the case for waste that has been produced before the existence of the waste acceptance criteria or for those wastes produced in small quantities, for which all the required information for acceptance cannot be provided. Acceptance of these waste packages for storage cannot therefore rely on pre-established requirements, such as waste acceptance criteria. A ‘case by case’ approach on their suitability for storage should be adopted, using all available information and taking into consideration the number of waste packages concerned. If further non-compliance with the criteria is the consequence and storage would not be safe, the determination has to be made that such waste requires additional treatment, characterization, conditioning, etc.

The store operator should ensure that appropriate processes are set up and implemented, involving auditing, inspection and testing, to ensure that waste packages meet the acceptance criteria for storage when they are received. Compliance of waste packages with WAC for storage should be verified immediately upon receipt of the waste package.

4.5.12. Audits

Auditing is a documented activity undertaken to determine by investigation, examination and evaluation of objective evidence that there is adequate adherence to established procedures, instructions, specifications, codes, standards, administrative or operational requirements, and other applicable documents.

The implementation and effectiveness of the Management System can best be verified through the auditing process. In general it is appropriate to separate audits into three categories:

(a) system audits;
(b) process audits;
(c) product audits.

System audits usually include process auditing and may also include product auditing. Process audits often include some product auditing.

4.5.12.1. System audits

System audits should:

- verify that the programme and plans address the applicable requirements;
- verify that the programme and plan(s) requirements are adequately addressed in operating procedures;
- verify that implementation of all quality control steps is adequate.

4.5.12.2. Process audits

Process audits are necessary to verify that the processes are being operated within specified boundaries which were initially fixed and that hardware is being controlled in a manner that meets design requirements. Process audits should focus on:

- assuring that important process variables have not changed from those values established in the original qualification;
- assuring that required inspections and applicable measurements using appropriate instruments are performed and that records are retained;
- verifying that traceability is maintained during transfer of waste and interim storage;
- assuring that instrumentation used to monitor or control waste processing has not degraded in service or has not been modified without approval;
- assuring that all important parameters of the waste packages are kept within established limits;
- assuring that the facility is being operated according to assumptions of the risk assessments;
- assuring that only containers qualified by performance-based testing are used and used only within their qualification limits.

Process audits are very beneficial in achieving quick improvement.

4.5.12.3. Product auditing

Product auditing usually involves the direct examination of the product, e.g. waste form, the waste container or the waste package. It is advised that the product auditing should be performed by an independent organization which possesses the testing and monitoring technology and expertise. Product auditing may also be performed when the product is sampled and examined within the processing facility for another purpose. Product audits may become the responsibility of the waste management organization when the waste producer lacks the infrastructure to perform quality control functions.

4.5.13. Management System review

The Management System adopted to satisfy all relevant regulatory requirements should be reviewed at appropriate intervals to ensure its continuing suitability and effectiveness. The regulatory body should review the development, implementation, maintenance and results of

audits of the Management System at appropriate intervals to ensure continuing compliance with regulatory requirements. The guidance and requirements for the review processes are provided in Refs [15, 17].

4.6. SUPPORT OF SAFETY ACTIVITIES OF THE OPERATOR

4.6.1. Radiation protection

The regulatory body is responsible for specifying the value of dose constraints, although applicants may additionally specify them in their internal rules. In any case, those who establish constraints should clearly describe the relevant source, and the magnitude of the constraint selected should be appropriate to the purpose in hand [38].

The choice of a value for a dose constraint should reflect the need to ensure that a critical group dose, both now and in the future, is unlikely to exceed the dose limit, with account taken of contributions of dose expected to be delivered by all other practices or sources to which the critical group is also exposed. More generally, the choice of the dose constraint should "ensure, for any source (including radioactive waste management facilities) that can release radioactive substances to the environment, that the cumulative effects of each annual release from the source be restricted so that the effective dose [and relevant organ or tissue doses] in any year to any member of the public, including people distant from the source and people of future generations, is unlikely to exceed any relevant dose limit, taking into account cumulative releases and the exposures expected to be delivered by all other relevant sources and practices under control" (Ref. [12], para. 2.26(b)).

The following provisions for radiation protection should be described:

- shielding (material, thickness);
- remote controlled tools (capacity);
- radiation monitoring systems;
- personnel dosimetry system.

4.6.2. Control of discharges

If discharges to the environment are foreseen by design of the waste management facility, the applicant should demonstrate that the discharges to the environment are part of a well managed and well designed operation.

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

- radionuclide composition;
- chemical and physical form of the radionuclides, particularly if this is important in terms of environmental or metabolic behaviour;
- routes of discharge and discharge points;
- total amount of the various radionuclides expected to be discharged per year;
- expected time pattern of discharge, including the need for and likelihood of enhanced short term discharges.

The next step is to establish which operational mode and associated discharge level is optimal in radiological protection terms.

For routine discharges of radioactive materials to the environment, the main types of control options are to provide either storage facilities for gaseous and liquid effluents, so that short lived radionuclides can decay before release, or treatment facilities that remove radionuclides

from the effluent stream for disposal by other means. Within these two broad categories there may be a number of different options available. The various options should be identified and their features examined as far as possible, including capital, operating and maintenance costs, the implications for waste management, and the effect on individual and collective doses for both the public and workers.

The applicant should ensure that during the operational period all radioactive discharges will be kept as low as reasonably achievable and report promptly to the regulatory body any releases exceeding any reporting levels or authorized discharge limits in accordance with criteria specified in the discharge authorization issued by the regulatory body [38].

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

The applicant should, where appropriate, establish and carry out monitoring programmes for effluents and environmental radiation. The purpose of these programmes is to ensure that the requirements established by the regulatory body in granting a discharge authorization are satisfied, and in particular that the assumptions about conditions in deriving the authorized discharge limits remain valid. The monitoring programme should enable exposures to critical groups to be assessed with the appropriate degree of confidence. The scale and scope of these monitoring programmes should be, as a minimum, in accordance with the guidelines set out in Ref. [38].

4.6.3. Emergency preparedness

The management of the predisposal radioactive waste facility is responsible for the safe operation of the facility. However, the possibility of radiological accidents that can lead to release of radioactivity to the environment and contamination of surrounding areas could not be completely ruled out. Experience has shown that emergency planning and preparedness are essential in order to respond effectively and mitigate the consequences of an accident.

The facilities that are part of a nuclear establishment having an approved emergency plan needs not to prepare a separate emergency preparedness plan rather these facilities should be included as a part of the existing emergency plan of the establishment. However, for the facility that stands alone in the area a brief description that will help in the preparation of emergency preparedness plan to be submitted to the regulatory body is given below.

4.6.3.1. Emergency classification

Radiological emergencies can be classified as:

(a) **on-site emergency**. Emergency whose effects will remain confined inside the facility and no effects will be observed outside the facility;
(b) **off-site emergency**. The emergency that will affect the public and environment.

4.6.3.2. Emergency preparedness plan

While not exhaustive, the following basic information should be provided in the emergency plan [21]:

- A brief description of the facility and the surrounding area.
- Identification of types of accidents for which protective actions may be needed.
- Classification of accidents.

- A description of off-site characteristics, including population densities, land use, industrial developments and transport arrangements.
- A system used to notify staff about emergency situations.
- A description of evacuation routes including assembly points.
- A brief description of the means and equipment for mitigating the consequences of each type of accident. A list of some of the equipment that may be required in handling the emergency is given below:
    - radiation monitoring instruments, e.g. high range survey meters (with extendible probes), low range survey meters, contamination monitors;
    - personal protective equipment e.g. direct reading dosimeters (DRDs), protective overalls, overshoes, gloves;
    - air monitoring instruments;
    - environmental sample monitoring instruments;
    - procedures for conducting monitoring;
    - weather monitoring instruments;
    - documents e.g. area maps, population information, copies of emergency plan, equipment operations manuals, procedures for personal radiation protection and other related documents;
    - communication equipment for emergency groups.
- A brief description of methods and equipment to assess radioactive releases.
- A brief description of the responsibilities of personnel, responsibilities for maintaining the equipment, and updating the plan.
- A brief description of the means to promptly notify off-site response organizations and request for assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate.
- A brief description of types of information on facility status, radioactive releases and recommended protective actions to be given to off-site response organizations and to the regulatory body.
- A brief description of means and methods for bringing the facility to a safe condition after an accident.
- A brief description of the intervention levels and the details for intervention implementation.
- A brief description of the frequency, performance objectives and plans for training to be provided to on-site personnel to prepare them for their responses to an emergency, including a radiological accident and for the orientation tours to fire, police, medical and other off-site emergency handling personnel.
- A brief description of conducting periodical communications checks with off-site response organizations and of regular exercises to test responses to simulated emergencies. (Exercises must use accident scenarios postulated as most probable for the specific site and the scenario should not be known to most exercise participants. Results of the exercise should be used to evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found must be corrected.)

4.6.4. Physical protection and security

To demonstrate to the regulatory body that the facility and radioactive materials are adequately protected and secured, the applicant should submit, on a confidential basis, the

description of the physical protection system established at the facility [22, 39]. This should include:

- a description of design features that have been adopted for the security of the facility;
- a description of equipment, methods and procedures to prevent the unauthorized entry to the facility;
- a description of measures to prevent the unauthorized removal of radioactive material from the facility;
- a procedure for authorizing the access to the areas where radioactive material is processed or stored;
- a brief description of the physical protection arrangements that will provide suitable security to the predisposal radioactive waste management facility.

The concept of physical protection requires a mixture of hardware (security devices), procedures (including the organization of guards and the performance of their duties) and the design of the facility (layout).

Given below are some techniques, regarding the physical protection of the facility, which will be useful for the security. Major of them are required to be adopted in the design phase. Necessary modifications could be made in the existing facilities to achieve the objective if it is not available in the existing design:

- Physical barrier (e.g. fence) could be provided surrounding the boundary of the facility.
- The entry gate should be strong enough to protect from any possible crash entry. A suitable barrier can also be provided at a suitable distance from the main entrance.
- Clear areas should be provided on both sides of the perimeter of the facility with illumination sufficient for assessment.
- Access points into the facility should be kept minimal.
- Persons authorized access to the radioactive material should be limited to persons whose trustworthiness has been determined. Persons whose trustworthiness has not been determined, e.g. temporary repair, service or construction workers and visitors, should be escorted by a person authorized unescorted access. The identity of all persons entering the facility and working inside the facility could be made using access control badges. Guards should be trained and adequately equipped for their function in accordance of national law and regulations.
- Dedicated, redundant communication system should be made available to the security personnel.
- All persons, packages and vehicles entering or leaving the facility should be subject to search.
- In addition, electronic devices such as closed circuit cameras, intrusion detection sensors can also be installed if required.

4.6.5. Fire detection and protection

Fire protection requirements shall be met by suitable incorporation of redundant parts, diverse systems, physical separation and design for fail-safe operation such that the following objectives are achieved:

(a) to prevent fires from starting;
(b) to detect and extinguish quickly those fires which do start, thus limiting the damage;
(c) to prevent the spread of those fires which have not been extinguished, thus minimizing their effects on essential facility functions.

The applicant should carry out a fire hazard analysis of the facility to determine the necessary rating of fire barriers. Provided fire detection and fire fighting systems of the necessary capability should be described.

4.6.6. Strategy for decommissioning

It is required to consider decommissioning requirements during design and operation of a predisposal radioactive waste management facility. In order to comply with this requirement a preliminary (or conceptual) decommissioning plan should be prepared at the stage of authorization. The decommissioning plan should be reviewed regularly and updated whenever required to reflect changes in the facility, changes in the regulatory requirements and advances in the technology. The main issues to be included in the preliminary (or conceptual) decommissioning plan are given below to provide some guidance in this respect:

- a description of funding arrangements;
- preparation for decommissioning during operation (e.g. provision of operational and monitoring records that may be needed for detailed planning of the future decommissioning);.
- a description of the planned decommissioning operations (including decontamination, dismantling and demolishing methods);
- management of radioactive waste resulting from decommissioning activities (including anticipated waste inventory, methods for waste minimization and provisions for disposal);
- post-decommissioning activities (e.g. a programme for final radiological survey of the facility and the site, a programme of environmental remediation of the site).

4.6.6.1. Funding arrangements

For funding of the future decommissioning of the facility estimation should be made by giving due consideration to the following decommissioning activities [40]:

- characterization of the facility and the site (initial and final radiological surveys);
- packaging, transport, storage and disposal of radioactive waste;
- decontamination of the facility if needed;
- dismantling and demolishing;
- post-decommissioning activities;
- schedule of the decommissioning and post-decommissioning activities;

4.6.6.2. Preparation for future decommissioning

Decommissioning is facilitated if planning and preparatory works are undertaken at the design phase of the facility and continues throughout the entire lifetime of the facility. This also includes the selection of suitable construction and structural materials to provide the easiness in the decontamination at the time of decommissioning. Description of these measures should be provided in the preliminary decommissioning plan.

4.6.6.3. Decommissioning operations

The major tasks that will be carried out during the decommissioning operation are:

- decontamination of the facility;
- treatment and packaging of the radioactive waste;
- transportation of radioactive waste to a disposal site (or transfer to a storage facility);
- release of material and items from regulatory control by clearance;
- removal of material and items for reuse or recycling.

Information about the presently available methods and techniques that will be adopted for the above mentioned decommissioning tasks should be provided in the plan. These methods and techniques depend on the type of the waste and the radioactivity it contains. However, the updating of the plan will be required with the advancement of technology with time.

4.6.6.4. Management of decommissioning waste

Decommissioning activities will generate large volume of radioactive waste over short time periods and the waste may vary greatly in type and activity and may include large objects. Therefore, due consideration should be given to the minimization (reuse, recycling, clearance) and further management of this waste. Appropriate methods, techniques that will be used for handling, processing and disposal this waste should be described in the decommissioning plan [41-43].

4.6.6.5. Post-decommissioning activities

The decommissioning plan should include the post-decommissioning arrangements so that the site could be released for unrestricted use. For this purpose a detailed radiological survey, after completing the decommissioning activities, is required to demonstrate the safe condition of the site. This survey report will be the part of the final decommissioning report that will be prepared after the decommissioning of the facility. The survey requirement and its methodology should also be provided in the plan.

All the aspects of the decommissioning activities (and intended schedule) should be correlated with the national strategy in the waste management field. If the operator is not able to prepare the decommissioning plan and other required documents, he can contract totally or partially the elaboration of documentation. The primary (input) data will be delivered by the operator.

4.6.7. Public involvement

The development of public involvement in the authorization processes is an important component of the democratic development of a country. In some countries public involvement is a major component of authorization while in others it is not considered at all. However, in countries where there is no tradition in public involvement it may be counterproductive to try to get the public involved and moreover it does not improve safety of the facility. In such situation public involvement should be restricted to public information where the applicant should ensure that the local population is fully informed on the facility.

Provided that there is a national tradition on public involvement in the authorization process and formal requirements exist in this regard, a full description of these requirements for public involvement and the actions taken or proposed should be given. The purpose is to provide assurance that the facility is acceptable to the public (where applicable, also to representatives from neighbouring countries). The following information should be provided by the operator:

- the description of a general strategy for the public information including the expected degree of public involvement and participation in decisions about the proposed facility;
- a summary of major comments received from beneficiaries, local officials, community leaders, NGOs, and others, and describe how these comments were addressed;
- a description of compliance with relevant regulatory requirements for public involvement;
- information about consultation with the neighbouring countries and a summary of major comments received (if applicable);
- a summary of public acceptance on the proposed facility.

The most sensitive issue for the public is usually the possible negative impact of a waste management facility or waste management operations on the environment. The actions to be taken in this regard by the applicant can be summarized as follows:

– an identification of milestones in the public involvement (e.g. dates, attendance, topics of public meetings), and recipients of the report and other facility-related documents;
– a description of other related materials or activities (e.g. press releases, notifications) as part of the effort to involve the public. This section should provide a summary of information disclosed to date and procedures for future disclosure.

5. CONCLUSIONS

This publication identified the authorization process, information requirements and provides guidance on the preparation of the required information that need to be addressed by the operators of existing or new predisposal waste management facilities when applying for an authorization and finally for an operational licence. The level and depth of the actual information provided will vary within each country and will depend on the risks associated with the processes, the complexity of the process and national legislation. If the operator of a waste management facility includes all of the identified information into the licence application, it will demonstrate his commitment to improving safety culture and enhancing safety appropriate with international standards. This will increase public confidence in the safety of the facility. It is expected that the operators of predisposal waste management facilities will find necessary details on how and where to obtain the required information.

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APPENDIX I.

PRELIMINARY SAFETY ASSESSMENT OF THE STORAGE FACILITY FOR DISUSED SEALED RADIOACTIVE SOURCES (RAKOVIČA, BOSNIA & HERZEGOVINA)

I.1. INTRODUCTION

The purpose of this assessment is to consider the safety aspects for the storage facility Rakoviča, Bosnia and Herzegovina (BOH). This facility was designed and constructed to provide the safe interim storage for conditioned spent sealed radioactive sources for a period until a suitable repository is available for final disposal. The maximum period of time anticipated for interim storage will not exceed 50 years. Temporarily, the facility will accept unconditioned spent sources until a conditioning facility is built and becomes available for conditioning operations.

This report is subdivided into sections that will consider those aspects that need to be taken into account when assessing the safety of the facility. Following this Introduction, Section 2 addresses the regulatory requirements for such a facility. Section 3 describes the methods used in the safety assessment for internal hazards, including hazard identification methods and the quantification of the hazards in terms of risks.

Section 4 indicates how the facility will be subdivided for the purpose of hazard assessment, while Section 5 reports on the actual internal hazard assessment. This follows in Section 6 by a description of external hazards. Section 7 uses data for releases during an event of close uptake and hence risks to operators may be evaluated. Section 8 assesses the risk to members of the public as a result of an aircraft crash.

The report finally provides some conclusions (Section 9) on the general risk arising from operation of the facility.

I.2. REGULATORY ARRANGEMENTS

The storage facility will meet the requirements of the national Law on Radiation Protection prepared in compliance with the IAEA BSS [1] that provides guidance for radiation protection.

The following principal limits are proposed for the design and operation of the storage facility:

(a) The design target for maximum whole body dose to an individual radiation protection worker is proposed as 15 mSv/year.
(b) The design target for maximum dose to the most exposed member of the public is proposed as 0.1 mSv/year.
(c) The design target for risks to workers on the site from accidental radiation exposures is proposed as 10^{-5} per year.
(d) The design target for an individual public risk from accidents is proposed as 10^{-6} per year.

I.3. SAFETY ASSESSMENT METHODOLOGY

In order to demonstrate that the facility complies with regulatory criteria, a safety assessment has to be carried out. Safety has to be addressed for both normal operations and accident conditions and the assessment needs to show that doses and risks remain within the criteria and the doses are as low as reasonably achievable (ALARA). Analysis of accident conditions has to consider the effects of those incidents arising from internal events, i.e. process related events and those incidents arising from external events, i.e. from events not related to the process.

Safety considerations for normal operations need to consider exposure, i.e. dose received, for different groups of individuals, namely operators in the facility and members of the general public living in the vicinity of the facility.

For accident conditions, it is normally required that the risk to an individual should be assessed. For the analysis of internal events, this would normally entail identifying the potential hazards, assessing the frequency of the accident occurring, calculating the consequences (in terms of dose) should the accident occurs and combining the probability and consequences to produce a risk; this would normally be done for each potential accident and summed for all accidents in the facility.

I.4. AREAS OF THE STORAGE FACILITY

This section describes how the facility is sub-divided prior to the safety assessment process. The various processes considered in the storage facility can be outlined below:

(a) source collection and transport to the storage facility;
(b) source receipt at the storage facility;
(c) source unpacking;
(d) temporary storage of a source;
(e) interim storage of conditioned sources.

I.5. SAFETY ASSESSMENT

The purpose of this section is to describe the main hazards identified in each of the above areas of the storage facility.

I.5.1. Source collection and transportation to the storage facility

The principal regulations for the safe transport of radioactive waste are those from the IAEA [2]. The national BOH transport regulations are based on the above document. Public and worker safety is assured when transportation is carried out in compliance with these regulations. The main requirements of these regulations of relevance for spent sealed sources for radiological protection relate to the surface dose rate (must not exceed 2 mSv/h) and contamination of the package (non-fixed, accessible contamination levels must not exceed 0.4 Bq/cm^2 for beta and gamma emitters and low toxicity alpha emitters or 0.04 Bq/cm^2 for all other alpha emitters).

The risk during the off-site transport of the collected sources should be seen as separate from that arising from the facility itself.

The main hazards during the on-site transport to be addressed will be:

(a) transport accidents during movements of sources across the site, covering packages falling off the transport vehicle causing damage to the package itself or other plant or services on-site;
(b) damage to the package itself from other activities on the site such as fires or falling objects;
(c) dropped loads during lifting movements causing damage to container;
(d) damage to the package during lifting from impacts with other objects, e.g. building walls;
(e) impacts.

Packages are designed to withstand all normal transport incidents during site movements, and any damage will be restricted by slow travel speeds. The possibility of dropping packages during lifting will be reduced by regular equipment testing and adherence to correct operating procedures. Equally important will be restriction of lift heights when moving packages to reduce the impact damage should they be dropped.

On-site transport operations will mainly be concerned with hazards to site personnel and operators.

I.5.2. Source receipt at the storage facility

Transport packages sent to the storage facility will be received in the receipt area where they will be off-loaded. Sources that arrive at the storage facility will be accompanied by appropriate documentation to indicate the type of sources in the package; this will enable storage facility staff to ensure it is sorted and stored in the most appropriate and safest manner.

The main hazards in the receipt area of the storage facility are considered to arise from:

(a) receipt of packages with higher than expected levels of radiation;
(b) receipt of packages with higher than expected levels of surface contamination;
(c) dropping of packages during transfer to the receipt area;
(d) collision of packages with building walls, etc.;
(e) impacts.

The above two faults are not expected to contribute a significant proportion to the total risk of the facility because the sources will be checked prior to their transportation to the storage facility. The last three hazards have already been discussed above.

I.5.3. Source unpacking

The principal hazards arising during unpacking will be due to contamination on the interior of the packaging; this could arise from inadequate packing or damage to the packaging during transport or handling. During the unpacking process there will be further monitoring of the packaging and the source prior to removal of the source so this should reduce the possibility of handling contaminated sources and packaging.

Other hazards to operators during unpacking could arise from the collapse of the source holder, possibly exposing sharp objects such as needles and glass; this can cause puncture wounds, which could give rise to an operator dose from contaminated materials.

I.5.4. Temporary storage of a source

The hazards arising from the temporary storage of sources are due to the fact that the sources are not contained in their transport packages. Those include the hazards due to:

(a) dropping individual sources during transfer to the receipt facility and during location on shelves/rack;
(b) deterioration of the source holder;
(c) inability of store shielding to provide adequate protection from sources;
(d) human error in placing higher dose rate sources in the normal part of the store.

I.5.5. Interim storage of conditioned sources

Faults which could give rise to hazards in the store include:

(a) dispatch of an externally contaminated drum to the store;
(b) dropped drum during movement to the store or within the store;
(c) failure of containment during storage.

Contamination of the drum can result from failure of a seal or sealing mechanism, overfilling of the drum or failure of the inspection system itself (usually human error). These risks are likely to be very small since the sources are sealed prior to encapsulation.

Hazards associated with transfer operations are similar to those described earlier, since the sources are immobilized, the potential hazards will be much lower.

The only other hazard would arise from degradation or failure of the drum containment; this could occur due to the use of sub-standard drums, damage to a drum after filling or corrosion or erosion in long term storage (either internally or from external condensation). The risk from this hazard would be very low since the low mobility of the activity would minimize any airborne contamination problems.

I.6. EXTERNAL EVENTS

There are two classes of external events — man-made and natural.

I.6.1. Man-made external events

I.6.1.1. Aircraft crash

The Sarajevo International Airport is located at a distance of 7-10 km from the storage facility, however, because the air traffic at present is low, the probability of an aircraft crash is also very low. Take-off and landing routes for airplanes are away from the location of the storage facility, and it is unlikely that a possible aircraft crash will affect the storage facility.

I.6.1.2. Missile impacts

The hazard of missile impacts should not be ignored because the store with explosive materials is located at a distance of 100 m from the radioactive store and in case of an explosion, the radioactive store might be affected in principle. However, two circumstances give this event a very low probability. Firstly, the explosive materials store has a very solid construction (made completely of the thick reinforced concrete) and secondly, the amounts of the stored explosives are very small — those serve as evidence at court.

I.6.1.3. Transport accidents

The transport activity that will involve explosive materials to be brought to the explosive materials store cannot be ignored. However, the probability of this event is very low owing to the factors discussed above.

I.6.2. Naturally occurring external events

I.6.2.1. Seismic events

The site is considered as potentially seismic. The last earthquake took place 20 years ago in this area. Since the sealed radioactive sources are planned to be stored in a conditioned form, i.e. the waste package resistant to severe impacts and heavy loads, a risk of spread of contamination due to an earthquake is very low. Additional protection will be provided by the construction of the building that was designed to withstand the earthquakes with a power up to 7 on Richter scale.

I.6.2.2. Extreme environmental effects

The magnitude of extreme weather conditions (T max. in summer, T min. in winter, Wind speed max. and Max. Snowfall-cm) should be provided. Maximum fog has been reported to be 10 m visibility in November-December period.

Lightning: The building is very well protected from lightning strikes — there are three lightning protective devices around the store.

Flooding: Regular maintenance of the drainage system will be carried out to prevent flooding.

I.6.2.3. Meteorite impact

Generally the impact due to meteorites is of significantly lower frequency than aircraft crash (about two orders of magnitude lower). The overall frequency has been estimated to be 1 per million square kilometres of the entire earth’s surface per annum.

I.6.2.4. Loss of services

Loss of services (failure of water and power supply) will not affect the safety of the storage facility, since these services are not required during static storing of conditioned spent sealed sources.

I.7. RISK TO OPERATOR EXPOSURE TO DIRECT RADIATION

Let consider a fault that is the accidental dropping of a source, either during receipt or transfer within the operational store. One assumption is that 0.4 TBq Co-60 source is considered. It may be possible to estimate the probability of an operator dropping a source during transit based on historical data.

For example, the probability may be estimated from historical data to be in 10 000 transfers; to this, the probability of the source breaking and exposing the contents should be added. This may be estimated to be 1 in 10 drops. Thus the probability of a source being dropped and exposing the contents will be 1 in 100 000 transfers. If there are 50 transfers per year, the probability of a source being dropped and exposing the contents will be 50 times 1 in 100 000 per year, i.e. 5 E-4 per year.

The Co-60 source if exposed will give rise to a direct radiation dose to operators in the vicinity; an assessment of the direct dose rate from such an exposed source is 85 mSv/h at a distance of 1 m, assuming a certain amount of source shielded. If it is assumed that the operator remains in the immediate area for one minute, the total exposure will be 85/60 mSv. Hence the risk to an operator for the dropped source will be

5×10^{-4}/year	×	$(85/60) \times 10^{-3}$ Sv	×	4×10^{-2}/Sv	=	2.8×10^{-8}/year
(frequency)		(dose)		(occupational dose-risk factor)		(risk)

That is not meant to represent a real risk, merely to provide a demonstration of the approach.

I.8. RISKS TO MEMBERS OF THE PUBLIC

Members of the public are unlikely to be affected by internally generated fault conditions in the storage facility. This is based on two considerations:

(a) Direct radiation doses are likely to be extremely low because of the sources involved and the separation distances from the boundary fence. Dose rates are likely to be small fractions of a μSv and thus even if fault conditions did occur, the resultant risks will be negligible.
(b) There are no mechanisms arising from fault conditions during operations whereby activity could be dispersed and result in exposure of the public.

However, it is possible that the external events such as an aircraft crash could result in activity being widely dispersed to affect members of the public. The probability of an aircraft is normally considered a remote possibility, but consideration should be given to its potential. Computer codes are available to predict site specific crash frequencies for aircraft (from a statistical analysis of aircraft crashes over a period of years) and for penetration of civil engineering structures as a result of aircraft impacts. Calculation of building aircraft crash frequencies requires details of the building dimensions and shielding provided by other facilities. The possibility of fire or explosion resulting from ignition of fuel should also be considered.

Based on knowledge from assessments of facilities that would be similar in size to the storage facility area, it is assumed that a background crash rate for the local conditions would give an aircraft crash frequency of the order 1 E-8 per year.

The assessment of off-site doses requires the knowledge of data on the inventory of materials, their release characteristics and calculation of their airborne concentrations at appropriate distances from their release. As with other consequence assessments, the air concentration can be converted to a dose with knowledge of the occupancy time, the breathing rate [3, 4] and the appropriate activity/dose conversion factors [5].

The following assumptions are made for the event of aircraft crash:

(a) release fraction of 5 E-4 for all nuclides;
(b) ground level release for 30 minutes;
(c) weather category 55% category D (Ref. 5) with rain for 10% of the time;
(d) members of the public located at a distance of 400 m from the release;
(e) pathways considered are inhalation, groundshine dose for 50 years and ingestion of foodstuffs from the same location;
(f) shielding factor of 0.5;
(g) dispersion averaged over 60^0.

The total estimated inventory of radioactive materials in the store after 10 years operation is given in Table 1, with calculated release amounts.

TABLE 1. NUCLIDE INVENTORY AND RELEASES

Nuclide	Total activity (Bq)	Release fraction	Total release (Bq)
Co-60	1.0 E13	5 E-4	5.0 E09
Cs-137	8.2 E11	5 E-4	4.1 E08
Ra-226	2.0 E10	5 E-4	1.0 E07
Am-241	2.8 E12	5 E-4	1.4 E09

The resultant doses are given in Table 2 and are conditional on the wind blowing into the sector. The dose factors from inhalation are taken from Ref. [6] while doses from external radiation were taken from Ref [7].

TABLE 2. CONDITIONAL DOSES TO MEMBERS OF THE PUBLIC AT 400 m

Nuclide	Conditional doses (Sv)			
	Inhalation	Groundshine 50 years	Ingestion 50 years	Total
Co-60	5.48 E-06	5.28 E-05	1.40 E-05	7.23 E-05
Cs-137	6.83 E-08	2.54 E-06	5.48 E-06	8.09 E-06
Ra-226	4.12 E-07	2.56 E-07	-	6.68 E-07
Am-241	1.92 E-03	3.34 E-07	2.81 E-05	1.95 E-03
Total	1.93 E-03	5.59 E-05	4.79 E-05	2.03 E-03

The highest doses are those to the adult in the critical group for inhalation. Using a risk factor of 5 E-2 per Sv and a uniform wind rose, the risk of premature death to a member of the public can be evaluated as

5×10^{-8} /year	×	2.03×10^{-3} Sv	×	5×10^{-2} /Sv	=	1×10^{-12} /year
(frequency)		(dose)		(public dose-risk factor)		(risk)

This represents an insignificantly small risk to members of the public.

I.9. CONCLUSIONS

For the storage facility Rakoviča, the volumes of material handled and the amount of radioactivity in the sources are likely to be relatively small. In general, the processes involved in the storage facility will be simple and would not normally involve extreme conditions such as high temperatures and pressures. As a result of this, the hazards arising in the storage facility are unlikely to result in major disruptive events anywhere in the process. The inventories of radioactive materials in the store will be low and even extreme events, such as those considered in Section 5 and 6, are unlikely to result in releases of radioactivity beyond the site boundary.

This report has attempted to discuss the various fault conditions to be considered in the operation of the Rakoviča storage facility. Most of the fault sequences are considered to be of low hazard potential.

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DEFINITIONS

The definitions given below may not necessarily conform to definitions adopted elsewhere for international use.

authorization. The granting by a regulatory body or other governmental body of written permission for an operator to perform specified activities. Authorization could include, for example, licensing, certification, registration, etc.

analysis. Often used interchangeably with assessment, especially in more specific terms such as safety analysis. In general, however, analysis suggests a more narrowly technical process than assessment, aimed at understanding the subject of the analysis rather than determining whether or not it is acceptable. Analysis is also often associated with the use of a specific technique. Hence, one or more forms of analysis may be used in assessment.

analysis, safety. Evaluation of the potential hazards associated with the implementation of a proposed activity.

assessment. The process, and the result, of analysing systematically the hazards associated with sources and practices, and associated protection and safety measures, aimed at quantifying performance measures for comparison with criteria. Assessment should be distinguished from analysis. Assessment is aimed at providing information that forms the basis of a decision whether something is satisfactory or not. Various kinds of analysis may be used as tools in doing this. Hence, an assessment may include a number of analyses.

commissioning. The process during which systems and components of facilities and activities, having been constructed, are made operational and verified to be in accordance with design specifications and have met the required performance criteria. Commissioning may include both non-radioactive and radioactive testing.

environmental (impact) assessment. An evaluation of radiological and non-radiological impact of a proposed activity, where the performance measure is overall environmental impact, including radiological and other global measure of impact on safety and environment.

environmental impact statement. A set of documents recording the results of an evaluation of the physical, ecological, cultural and socioeconomic effects of a planned facility (e.g. a repository) or a new technology.

facilities and activities. A general term encompassing nuclear facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources. [Safety Series No. GS-R-1].

licence. A legal document issued by the regulatory body granting authorization to perform specified activities related to a facility or activity. The holder of a current licence is termed a licensee**.** A licence is a product of the authorization process, although the term licensing process is sometimes used.

nuclear facility. A facility and its associated land, buildings and equipment in which radioactive materials are produced, processed, used, handled, stored or disposed of on such a scale that consideration of safety is required.

operating organization. The organization (and its contractors) which undertakes the siting, design, construction, commissioning and/or operation of a nuclear facility.

operation. All activities performed to achieve the purpose for which a facility was constructed.

operator. Any organization or person applying for authorization or authorized and/or responsible for nuclear, radiation, radioactive waste or transport safety when undertaking activities or in relation to any nuclear facilities or sources of ionizing radiation. This includes, inter alia, private individuals, governmental bodies, consignors or carriers, licensees, hospitals, self-employed persons, etc. [Safety Series No. GS-R-1]. (Synonymous with operating organization.)

performance assessment. Assessment of the performance of a system or subsystem and its implications for protection and safety at a planned or an authorized facility. This differs from safety assessment in that it can be applied to parts of a facility, and does not necessarily require assessment of radiological impacts.

regulatory body. An authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby for regulating the siting, design, construction, commissioning, operation, closure, decommissioning and, if required, subsequent institutional control of the nuclear facilities (e.g. near surface repository) or specific aspects thereof.

safety. The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards.

safety assessment. Analysis to evaluate the performance of an overall system and its impact, where the performance measure is radiological impact or some other global measure of impact on safety. (See also assessment, performance.)

safety case. An integrated collection of arguments and evidence to demonstrate the safety of a facility. This will normally include a safety assessment, but could also typically include information (including supporting evidence and reasoning) on the robustness and reliability of the safety assessment and the assumptions made therein.

safety report. A document required from the operating organization by the regulatory body containing information concerning a nuclear facility (e.g. a waste repository), the site characteristics, design, operational procedures, etc., together with a safety analysis and details of any provisions needed to restrict risk to personnel and the public.

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