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**Guidance on  
radioactive waste management legislation  
for application to  
users of radioactive materials  
in medicine, research and industry**

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**GUIDANCE ON RADIOACTIVE WASTE MANAGEMENT LEGISLATION  
FOR APPLICATION TO  
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## FOREWORD

It has been observed by IAEA Technical Co-operation experts and advisory missions to developing countries in radioactive waste management and radiation protection, particularly Waste Management Advisory Programme (WAMAP) and Radiation Protection Advisory Team (RAPAT) missions, that there is no uniform approach in the understanding and implementation of radioactive waste management systems - from generation of waste to disposal - in different countries. It is necessary to ensure a global uniformity in the approaches to finding solutions for the safe management of radioactive wastes.

One of the basic requirements in implementing a safe radioactive waste management regime is that all countries should have adequate legislation for managing radioactive wastes. In countries where laws exist, experienced personnel are lacking to implement them, supported by relevant regulations and guidance documents. In many countries the necessary laws and regulatory framework are lacking. It is estimated that there are more than 60 countries having totally insufficient radiation protection and waste management infrastructures which encompass laws and regulations that are the basis on which these infrastructures are developed. This is particularly the case in countries which do not have a nuclear power programme, nuclear research reactors or a long experience of work with radiation sources. There is a basic need to improve the situation in this respect.

In 1988 the Waste Management Section of the Division of Nuclear Fuel Cycle and Waste Management prepared a report for discussion on "Guidance on the Requirements for Radioactive Waste Management Legislation for Application to Users of Radioactive Material in Medicine, Research and Industry". The report was meant to be used for discussion and obtain comments of IAEA staff members and concerned authorities in developing countries. It was prepared by a consultant, Mr.C. Bergman of Sweden, with the assistance of Messrs. G.S. Linsley, J. Rames, K.T. Thomas and E.A. Westerlund of the IAEA.

The report has been extensively used by IAEA staff members in their contacts with developing countries and in IAEA training courses and workshops. The report was reviewed by Mr. S.D. Soman of India, Mr. F.J. Turvey of Ireland, Mr. J. Pahissa-Campa of Argentina and Mr. F. Lopez-Lizana of IAEA. Based on their comments and development in the field as well as feedback from some countries on the earlier draft, the report has been revised by Mr. K.T. Thomas and is being published as an IAEA-TECDOC to facilitate its further use.

### ***EDITORIAL NOTE***

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## 1. INTRODUCTION

The goal of radioactive waste management is to protect man and his environment from undue exposure to ionizing radiation from radioactive wastes. This is achieved by waste management practices which comply with the general radiation protection requirements as described in ICRP Publication 26 [1] and IAEA Basic Safety Standards [2]. Recently the ICRP has adopted new recommendations on radiation protection [3] and as a consequence the Basic Safety Standards will be revised.

Based on information from Member States and experiences of RAPAT missions, the Agency has already published an internal document on "Radiation Protection Legislation and its Implementation" [4]. It deals with general organization of a radiation protection regime applicable to a country. In order to ensure, however, that the Agency is consistent in different documents, the present document is using the same basic approach but with emphasis on questions related to waste management.

Radioactive waste management including disposal, is part of and the final step in the use of radionuclides. It cannot be justified by itself but only as part of the benefits of the uses of radionuclides in medicine, research and industry. The Waste management legislation must be seen along with the general radiation protection, atomic energy or other relevant national legislation regulating the safe use of radionuclides and the protection of man and his environment from undue exposure to ionizing radiation. Normally it will suffice if a special section on waste management is included in such legislation. If no such national legislation exists, it is necessary to create a legislative system covering all aspects of management and disposal of wastes arising from the uses of the radionuclides. No use of radionuclides should be permitted unless the radioactive waste arising from such a use can be managed in an acceptable way.

In this document on waste management legislation, in order to be self contained, many items which already would have been regulated in a general radiation protection document have been included. For such items therefore, this document should be seen



only as a check list as there should not be any contradiction in the legislative details. Further, there should preferably be the same Competent Authority for radiation protection and radioactive waste management.

## **2. SCOPE**

This document, addressed primarily to developing countries, is restricted to management of radioactive wastes arising from uses of radionuclides in medicine, industry and research. It does not deal with wastes from the nuclear fuel cycle. Safeguards and physical protection are also outside the scope even though in some special cases it may be relevant; for instance, when fissile material is handled at research establishments. Information on nuclear fuel cycle waste management and waste transport can be found in a number of IAEA publications [5-9].

The main aim of this document is to give guidance on legislation required for safe handling, treatment, conditioning and release or disposal of radioactive waste. It covers all steps from the production or import of radioactive material, through use, treatment, storage and transport, to the release or disposal of the waste either as exempted material or in special repositories.

Management of radioactive wastes as a whole is optimized and kept at acceptable levels in accordance with the basic ICRP recommendations [1] and the IAEA Basic Safety Standards [2]. As a result of the new ICRP recommendations of 1991 [3], the Agency is revising its Basic Safety Standards, the results of which may have some impact on the national regulations and necessitate updating of this document.

## **3. OUTLINE OF A GENERAL WASTE MANAGEMENT REGIME**

Safe waste management practices, and their implementation, should be based on:

- Government policy i.e. to protect man and his environment from undue exposure to ionizing radiation from radioactive waste;

- a legal framework i.e., legislation and guidance, to give effect to government policy;
- the necessary resources to administer the legislation i.e. organizational, financial, technical and expertise.

#### **4. WASTE MANAGEMENT POLICY**

There should be a clearly expressed national policy. The objective of the policy should be that adequate protection should be given to man and his environment from undue exposure to ionizing radiation from radioactive waste by the application of up-to-date internationally accepted waste management and disposal methods. In establishing and keeping the policy under review, the government should be advised by appropriately qualified persons whose collective expertise covers all relevant disciplines.

#### **5. LEGISLATION AND GUIDANCE ON RADIOACTIVE WASTE MANAGEMENT**

In most countries, legislation comprises primary legislation and subordinate legislation, the provisions of which are legally binding. Primary and subordinate legislation is usually supplemented by Guidance documents (which may, for example, be called Codes of Practice) issued by, or under the authority of, the responsible governmental authorities. Such guidance documents give practical recommendations and possible ways in which the specific legal requirements of the primary and subordinate legislation could be met. As such documents do not specify legally binding requirements they do not form part of the legislation, but are valuable supplements to the legislative regime. Any document containing provisions which are legally binding will be a legislative document rather than a guidance one. Fig. 1 illustrates the hierarchy of legislative and guidance documentation.

- Primary legislation:  
For easy reference, "Primary Legislation" will henceforth be referred to as "the Law". A Law is issued by the supreme law-making authority of the country (e.g. Parliament), provides the legal basis for regulating waste management (may be part of a Law

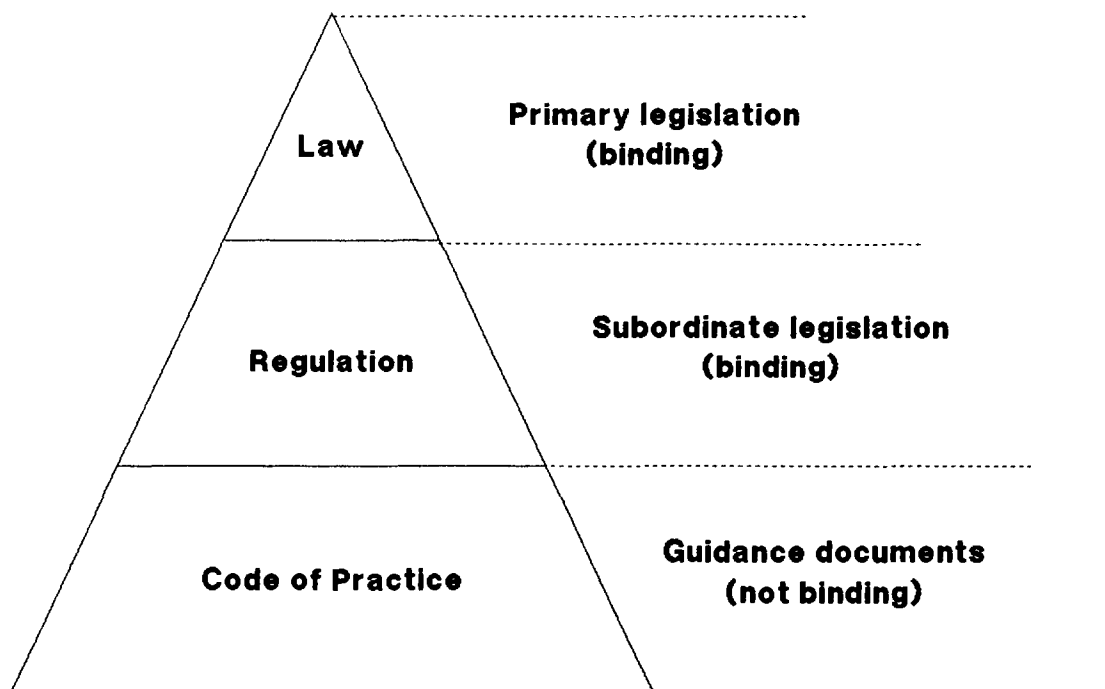


FIG. 1. Hierarchy of legislation and guidance.

on Radiation Protection or Atomic Energy) in conformity with government policy, and normally includes the general principles of waste management. The Law also authorizes the issuance - by a Government Minister or other Competent Authority - of subordinate legislation specifying the particular requirements to be observed to achieve the general principles of waste management.

- Subordinate legislation:

For easy reference, "subordinate legislation" will henceforth be referred to as "Regulations" (in some countries called "Decrees"). These are issued by a Government Minister or other Competent Authority specified under the Law. They establish the general principles (if not already established by the Law referred to above); the waste management strategy and planning; and specify the particular requirements necessary to achieve effective waste management in accordance with the provisions of the Law governing waste management. Regulations are normally of general

application, but the Law may authorize the issuance of site-specific Regulations. However, even Regulations of general application may authorize the imposition of site-specific conditions and requirements.

- Guidance documents for the implementation of regulations give instructions and technical details on the different parts of waste management to comply with the regulatory requirements. They are normally issued by the Competent Authority.

The manner in which Laws, Regulations and Guidance documents are combined to provide an effective regulatory framework for waste management is a matter for the country concerned. This may vary from one country to another depending on its structure, governmental organization, legal traditions and regulatory practices.

In this document no sharp distinction is made between items to be dealt with by the Law and those to be within the Regulations. The outlines which follow are merely aimed at covering the various items involved. Furthermore, the document does not make any distinction between what should be outlined in a special waste management legislation - as described in this document -, and what should be covered in other legislations on general Radiation Protection or Atomic Energy. Most of what is stated, especially in Section 5.1, could be covered in a general radiation protection legislation.

Normally, a Law is adopted following an extensive and formal legislative process and any amendments to it are subject to the same procedures. Laws are therefore not usually expected to be modified frequently as this generally requires a time-consuming process. However, Laws and Regulations may need amendment as a result of changes in the national use of radioactive material, technical development, changes in national waste management policy or evolution over time of the radiation protection standards and goals. The procedure for issuing and amending Regulations is generally simpler and less time-consuming. Hence, it is advisable to include technical requirements, which are likely to be subject to frequent change, in the Regulations rather than in the Law.

## 5.1 Law

For the purpose of achieving safe management of radioactive waste, the Law should give the basis for:

- o setting the goal for protection of the worker, the general public and the environment by:
  - establishing, where appropriate, a multidisciplinary advisory body to assist and advise the Government and the Competent Authority in matters relevant to waste management
  - the formulation and review of a national policy or national strategy for waste management
  
- o establishing a Competent Authority responsible for regulatory control and enforcement.
  
- o licensing the following activities involving radioactive material<sup>1</sup>
  - production
  - import and export
  - trade
  - possession
  - handling
  - use
  - treatment/conditioning
  - storage
  - transport
  - disposal
  
- o exempting under proper control and within nationally approved 'exemption' limits small quantities of radioactive material from all or part of the waste management regulatory system.

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<sup>1</sup>Based on ICRP publication no. 60 of 1991 the Agency's Basic Safety Standards are being revised. This revision will have changes in licensing, notification and even 'exemption' which may necessitate updating the document later.

The Law must in addition:

- o give all the necessary definitions of terms used in the Law;
- o empower the Competent Authority to propose or issue Regulations where appropriate, in co-operation or consultation with other concerned national organizations;
- o vest the Competent Authority with the rights of access to, and inspection of, premises, facilities and equipment involving radioactive waste to ascertain compliance with the requirements of the legislation;
- o set forth penalties or applicable sanctions for violations of the Law and Regulations.
- o allow for appeal against decisions made by the Competent Authority.

As mentioned earlier, many of the above items in a Law regulating waste management are the same as in a law regulating radiation protection or the appropriate national law regulating other use of radioactive material. Further, in a country with a small programme involving use of radioactive material, often the same individuals are involved in both use of radioactive material and management of the waste arising from that use. These are some of the reasons for including waste management legislation in a general Law on radiation protection.

There may be other national Laws which can affect waste management. Examples of such Laws are:

- Law regulating environmental pollution
- Law regulating the working environment
- Law regulating disposal of hazardous material.

Even though it may not be reasonable or appropriate to draft a single integrated Law covering all aspects of waste management, it is nevertheless necessary to ensure that the various laws dealing with waste management are consistent and regulate all aspects of waste management.

An example of a text of a generic Law for radioactive waste management is given in Attachment A.

## 5.2 Regulations

Regulations give specific requirements for waste management according to the principles laid down in the Law but within the limits of the Law. There may be one or more sets of Regulations for the implementation of the Law. Preparation of Regulations may require extensive co-operation and consultations with other organizations, which is facilitated if there exists an advisory body. It may, however, be difficult in some countries to set up such an advisory body. In those cases the organization preparing the Regulations must find other means to ensure that the Regulations cover all necessary aspects and do not conflict with other Regulations.

Regulations on waste management should cover the following:

- o Licensing procedure
- o Procedure and criteria for 'exempting' waste from further regulatory control
- o Directives on
  - radiation protection goals and philosophy
  - waste management strategy
  - waste characterization
  - treatment and conditioning
  - monitoring, documentation and reporting
  - transport
  - quality assurance
  - storage
  - emergency preparedness
  - disposal
  - institutional control of disposal sites

Attachment B gives details of what could be covered in a regulatory text. It is only an example and depending on the national situation additional paragraphs may have to be introduced or existing ones modified. In some circumstances, some parts of the text could be included in the Law.

Further information relevant to Regulations on Waste Management and transport of wastes can be found in IAEA publications [6-9].

### **5.3 Guidance documents for implementing the regulations**

Guidance documents for the implementation of the Regulations (in some countries called Codes of Practice, Rules or Directives) are not legally binding. They are used by the Competent Authority to give recommended detailed operational and technical standards or criteria generally applicable to specific practices to ensure that the objectives of the law and regulations are achieved. The Guidance documents will be subject to revisions and amendments as a result of changes in the national use of radioactive material, technical developments, changes in national policy and evolution over time of national and international radiation protection standards, goals and policies.

The level of detail in the Guidance documents may vary from country to country. In some countries recommended operational and technical standards or criteria are given by the Competent Authority on a case by case basis. Such a system however is not generally recommended since even with qualified and experienced personnel employed by the Competent Authority there is always a risk that uniformly judging on a case by case basis comparable recommended standards or criteria is often difficult. A general approach should therefore be to have generally applicable technical and operational standards or criteria in the form of written guidance with possibilities for revision or amendments as needs arise. The written guidance need not be very detailed and should not be written in such a way that practical application and development of new methods and techniques are made too difficult.

There are a number of areas within waste management legislation which call for guidance for their implementation. Some of these may be identical to the corresponding guidance for the general radiation protection legislation.

Besides the items discussed in 5.2, which should be covered in detail in the guidance, there will also be other items which should



be recognized by the Competent Authority such as:

- volume reduction principles and methods
- procedures for dealing with consumer products, liquid scintillation solutions, apparatus with sealed radiation sources, and radium-226 sources used in medicine.

Further information on the subject can be obtained from existing guidance, Codes of Practice and recommendations issued nationally and by international organizations, notably the IAEA, on various aspects of waste management.

## **6. RESOURCES**

Resources are needed for the implementation of a national waste management legislative regime. Some of the important ones are: financial resources, facilities, equipment, manpower and 'knowhow'. There are resources which could be the same or shared with the resources needed for a general radiation protection regime in the country.

It is not possible to give details on all resources needed in a country since the needs depend on the national situation. In general terms, the resources should be adequate to comply with the requirements set up for the waste management regime.

### **6.1 Financial resources**

The Competent Authority will need, and must have, financial resources in order to function effectively in accordance with the national plan for waste management. The resources can be provided from the national budget, from fees paid by the waste producers and users of the services provided by the authority, or by a combination of national budget and fees, depending on national policy. If a significant part of the financial resources is provided by the national budget, it should be ensured that the Competent Authority is allowed to function independently irrespective of the quantum of government funding.

In most countries, the users of radioactive materials are responsible for the safe management of their radioactive wastes in accordance with the Law and Regulations. Therefore, it is important that such users should have the necessary financial resources to do the work. This should be considered in advance when planning the use of radionuclides. However, the State should ensure by appropriate means availability of funds to deal with abnormal situations when a user due to bankruptcy or for some other reason does not have the financial resources to take care of the radioactive waste. Otherwise radioactive materials may end up in places where they can endanger the health of people.

## **6.2 Facilities**

Facilities include buildings, laboratories, waste treatment and storage installations and waste disposal sites. They should be constructed to comply with the specific requirements, existing or foreseen, of the local or national needs of waste management. The impact on waste management facilities from planned changes in the use of radionuclides, notably increased volumes of radionuclides used or new application areas, must be analyzed and all necessary modifications or required new facilities must be implemented in a timely manner to comply with the changed requirements when they occur. In order to manage short-term increases in waste volumes to be processed, e.g. as a result of an incident, the design capacity of the facilities should be higher than required for normal operations. The extent of the increased capacity should be based on an optimization of waste treatment methods, efficiencies and radiation protection. Experiences in other countries could give some guidance. It is the responsibility of the user to provide adequate capacity, and of the Competent Authority to ensure that it is adequate for the normal, and in case of an incident, additional needs of the user.

## **6.3 Instrumentation and Equipment**

The required instruments for implementing a waste management legislative regime should be available. Examples of instruments needed are: surveillance monitors, special radiation detectors, detectors for activity measurements, and calibration sources.

It is the responsibility of the Competent Authority to ensure that the license holders have all the necessary instruments and that it is suitable for the license holder's purpose. For example, in laboratories handling alpha emitting radionuclides, it is not enough to have instruments measuring only beta and gamma radiation. Additional special monitors may be required for weak gamma emitting radionuclides, like  $^{125}\text{I}$  and for weak beta emitters like  $^{14}\text{C}$  and  $^3\text{H}$ .

The Competent Authority should secure for itself the best instruments available, or should have access to them. This does not mean that the most expensive and sophisticated equipment should be procured. In most cases it is preferable to have less sophisticated (and cheaper), but reliable instruments which comply with the requirements needed, since they are often less sensitive to failure. Also, such factors as ready availability of service and maintenance facilities are important and should be given due consideration.

The Competent Authority should investigate the availability to have access if needed of special instruments that may be needed in, for instance, emergency situations. Examples of such instruments and equipment are: additional radiation protection monitors, shielded transport containers, decontamination equipment, and remote handling devices.

#### **6.4 Manpower and 'know-how'**

For the implementation of waste management legislation, it is necessary to have the required manpower with the right combination of education qualifications and practical experience. There are needs for professionals and technicians at different levels an effective combination of which should constitute a qualified work force; both at the levels of user and Competent Authority. While theoretical expertise is important, practical aspects should be given equal importance. Staff should be capable of tackling problems as they arise which may require approaches both at scientific and practical levels for their solution.

A combination of regular training and education of the existing and newly recruited staff are necessary to maintain a well functioning team. It is the responsibility of the management to ensure that the personnel have the qualifications needed to perform their jobs in a safe, efficient and professional manner at all times. This underscores the need for re-training of personnel.

## **7. SPECIAL COMMENTS**

Due to various reasons such as lack of waste management legislation, adequate waste management practice or disposal sites, large quantities of waste may be kept under storage in many countries. Often, there may not be proper documentation for the stored wastes and the interim storage facilities may not be in accordance with good waste management practice. Such stored waste should be identified, categorized and conditioned in accordance with established international practice.

The process of identification and characterization of unknown radioactive waste is complicated. It includes identification of radionuclides in the waste and measurements of the activity, which often requires sophisticated instruments and qualified expertise.

Countries with such stored unidentified waste, and which do not have qualified experts in the field of measuring and identifying unidentified radionuclides, are recommended to seek the assistance of the IAEA.

Experience has shown the need for a national register of sealed radiation sources. Such a register can be used by the authorities as a check list for regular control of the sources which may represent a risk resulting in serious health effects, if not handled properly. It is not possible to give exact criteria as to what sources should be included in a national register. If too many sources are registered there will be difficulties in keeping the register updated. Also, it may cause difficulties in finding quickly the most hazardous sources among all listed. If on the other hand, too few sources are included, there is a risk that some sources of significance may have been overlooked from the special control system. As a guide it can be recognized that sealed

sources with an activity content below a few MBq are most unlikely to give rise to deterministic health effects and further the probability for stochastic effects is reasonably small. On this consideration, national registries may exclude (a) short lived sources, (b) instrument check and calibration sources (other than plutonium containing sources), etc. It is the responsibility of the national Competent Authority to decide what has to be included. A national register should supplement and not replace registers and other documentation which are required to be kept by the users, according to national legislation.

As a rule long lived wastes such as spent radium and caesium sources should not be disposed of by users in their premises. They should be handed over to the relevant National Authorities for appropriate long term storage and ultimate disposal according to IAEA guidance and recommendations.

Procedures for decommissioning and consequent disposal of wastes from large radiation facilities (teletherapy units and industrial irradiation, consumer product manufacturing facilities, etc.) should be covered in the Guidelines.

The attachments to this report give general guidelines for countries to develop and promulgate the necessary legislative framework for safe management and disposal of radioactive wastes.

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- [9] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 1985 Edition (As Amended 1990), Safety Series No.6, IAEA, Vienna (1990).

## **Attachment A**

### **GUIDANCE ON A LAW ON RADIOACTIVE WASTE MANAGEMENT**

(See Section 5.1)

#### **GENERAL REMARKS**

It is not possible to give a generally applicable text of a Law for regulating radioactive waste management. Such a text will differ from country to country since it must be in conformity with the national legal tradition and shall also comply with specific national requirements on the subject. Furthermore, it should be part of or in consonance with existing general Laws on Radiation Protection or Atomic Energy.

The following example of legal provisions on radioactive waste management should be included in the National Atomic Energy or Radiation Protection Laws. If such Laws do not exist, a separate special Waste Management Law will be necessary. However, for the sake of completeness, the following example is written as a self-contained text thus including many items which should appear in a Radiation Protection or Atomic Energy Law which, if in existence, precludes the need for a special waste management Law. The repetitions should be seen as a checklist.

The text of the Law given is intended to be illustrative only and should not be used directly for application in any particular country. A national Law can be drafted with the help of this attachment only after an evaluation of the national situation by the technical authority and in conjunction with the legal authorities in the country concerned.

## EXAMPLE OF PROVISIONS TO BE INCLUDED IN A LAW

### I. Object

To regulate and control the management of radioactive waste so as to protect man and his environment from undue exposure to ionizing radiation from such waste.

### II. Definitions

For the purpose of the Law, the definitions to be included will reflect national practices. The legal authority responsible for the drafting of the legislation will include all such definitions. Generally speaking, such of those words or phrases (particularly technical words or phrases) whose definitions will facilitate a clear understanding of the Law should be defined. Given below are typical examples (not conclusive) of definitions of some terms that should be included. For more information, IAEA Radioactive Waste Management and Radiation Protection Glossaries should be consulted [1] [2].

"radioactive waste management":

All activities, administrative and operational, that are involved in the handling, treatment, conditioning, transportation, storage and disposal of waste.

"special waste management facilities":

A waste management facility or a significant part of a plant intended for a special purpose, such as for example interim storage, treatment or conditioning of radioactive waste. (Small interim storage and treatment facilities which are directly connected to a workplace should be covered by the license for use of radionuclides at that work place and should not be subject to separate licensing under the waste management law.)

"radioactive waste":

Any material that contains or is contaminated with radionuclides at concentrations or radioactivity levels greater than the 'exempt' quantities established by the Competent Authorities and for which no use is foreseen.



"radioactive material":

A material of which one or more constituents exhibit radioactivity, etc.

### **III. Basic Provisions**

Radioactive waste management shall only be conducted in conformity with the requirements of this Law, and with the requirements of other Laws governing radiation protection and those relating to the working environment, environmental protection, transport etc. as specified in the following: .....

### **IV. Competent Authority**

The Minister for ..... is responsible for matters related to this Law. For the implementation of this Law, the Minister shall issue or authorize issue of Regulations and supporting Guidance documents and establish a Competent Authority empowered to carry out supervision and inspection.

The Minister may authorize an existing or new body established under this Law to issue Licences, Regulations and Guidance, specify conditions, and conduct supervision and inspections for the implementation of the Law. This body should be the Competent Authority for radioactive waste management. (Whether such a provision should be included, and the assignment of powers between the Minister and the Competent Authority, will depend on national circumstances. This Attachment and Attachment B should be read in the context of this comment.)

The Minister may establish a multidisciplinary advisory body to advise and assist the Minister and the Competent Authority in matters relevant to waste management, including formulation and review of the national policy or strategy for waste management.

The Minister (or the Competent Authority) may, by regulation, 'exempt' quantities of very low level radioactive material from the requirements of this Law. (Such 'exemption' will not necessarily affect the application of any other relevant existing national legislation(s) to radioactive material exempted from the requirements of this Law).

## **V. Licences**

A Licence is required under this Law for radioactive waste management. The applications to be submitted by the users shall be reviewed and considered by the Competent Authority except for construction of a disposal facility which shall be considered by the Minister or by an Authority designated by him for this purpose.

The Competent Authority may, if it so decides, require licencees to apply for a special Licence under this Law for termination and closure of a facility where radioactive wastes have been treated, conditioned or stored.

The licensing procedure shall be as specified in the Regulations.

## **VI. Conditions and Inspections**

When a licence is issued or during the period of validity of a licence, such conditions may be stipulated as are required from a radiation protection or safety point of view by the Competent Authority.

Supervision and inspection to ensure compliance with this law, regulations or conditions issued pursuant thereto shall be exercised by the Competent Authority.

The licence holder shall at the request of the Competent Authority:

- give such documents and information as are needed for the supervision
- allow the authority admittance to the facility or site where waste management is conducted to the extent required for the supervision.

## **VII. Responsibility**

The user has the responsibility for management, and for ensuring safe disposal, of all waste generated during and due to

his use of the radioactive material. However, the responsibility for disposal could be entrusted to a centralized national authority or facility under the control of the Competent Authority.

#### VIII. Revocation of Licences

The Competent Authority may revoke a licence if:

- stipulated conditions or directives have not been observed in some respects which are essential for radiation protection or safety
- there are other particular radiation protection or safety reasons.

#### IX. Appeal

Appeal against decisions taken by the Minister or the Competent Authority under this law shall be lodged with ...

#### X. Sanctions

The sanctions for violations of this Law and Regulations issued thereunder and of decisions made by the Competent or National Authority according to this Law and Regulations issued thereunder shall be stated in accordance with national legal traditions and practices taking into consideration the seriousness of the violations and their effects.

## **Attachment B**

### **GUIDANCE ON REGULATIONS FOR RADIOACTIVE WASTE MANAGEMENT**

(See Section 5.2)

#### **GENERAL REMARKS**

Even if the structure and content of a law may differ from country to country, the law normally only gives the legal basis for detailed Regulations. It is therefore necessary to issue Regulations as a supplement to the law in order to give general principles and requirements governing waste management. Even Regulations can differ with regard to structure and content. A single regulation can cover the whole area, or a set of regulations may be issued each covering a limited subject, but together covering the whole area. It is also important that a Regulation on radioactive waste management is in conformity with regulations on radiation protection.

The following example of a regulatory text on waste management, is written as a single Regulation, leaving most details of applications to be covered in the guidance documents. It is written as a self-contained document even though many of the items may also be discussed in a corresponding document on radiation protection. Unnecessary duplications can be excluded in a specific situation where regulations on radiation protection exist. The repetitions should be seen as a checklist.

The following text is intended to be illustrative only and should not be used as the text of a Regulation for radioactive waste management in any particular country. Such a text can be prepared with the help of this attachment only after an evaluation of the national situation by the technical authorities in conjunction with the legal authorities in the country concerned.

## EXAMPLE OF PROVISIONS TO BE INCLUDED IN A REGULATION

### I. Definitions

The following definitions are only examples. Additional definitions may be required according to the national needs. For more information, IAEA Radioactive Waste Management and Radiation Protection Glossaries should be consulted [1] [2].

**applicant:** The individual or organization that applies for a licence to perform specified activities with radioactive substances.

**treatment of waste:** Operations intended to improve safety or economy by changing the characteristics of the waste. Three basic treatment concepts are:

- (a) volume reduction;
- (b) removal of radionuclides from the waste;
- (c) change of composition.

**collective dose:** Collective effective dose equivalent (SE), which is the integrated products of the effective dose equivalent and the number of exposed individuals.

**conditioning of waste:** Those operations that transform waste into a form suitable for transport and/or storage and/or disposal. The operations may include converting the waste to another form, enclosing the waste in containers, and providing additional packaging.

**disposal:** The emplacement of waste in a repository, or at a given location, without the intention of retrieval. Disposal also covers direct discharge of wastes into the environment with subsequent dispersion.

**individual dose:** Effective dose equivalent to an exposed individual.

quality assurance: Planned and systematic actions aimed at providing adequate confidence that an item of a facility will perform satisfactorily in service.

storage (or interim storage): Storage of radioactive materials such that:

- (a) isolation, monitoring environmental protection and human control are provided; and
- (b) subsequent action involving exemption, treatment, transport and disposal or reprocessing is expected.

## **II. Licensing Procedure**

The applicant may be an individual, or organization (company, institute, etc.)

The applicant shall submit the application with all the relevant information to the competent authority. (The regulations should specify the information required to be submitted with the application.)

The applicant shall, if required, give all the support and complementary information needed by the competent authority.

The regulations should also specify the time limits within which actions under the licensing procedures are to be taken.

Annex I of this attachment gives details of information to be provided in an application for Licence for import of radionuclides and waste management.

## **III. Function of the Competent Authority**

The Competent Authority shall scrutinize applications and whenever needed require supporting and complementary information. The Competent Authority may issue a licence subject to conditions, etc. to be complied with by the licensee.

The Competent Authority shall give all necessary conditions, instructions or guidance for a given licence.

The Competent Authority shall through inspections and reports ensure that waste management activities are performed in accordance with the law and whenever needed, specify complementary or new regulations, conditions and guidance.

The Competent Authority shall have access to the premises, facilities and equipment licensed or subject to licensing, as well as to all relevant documentation.

#### **IV. Basic Radiation Protection Principles**

The radiation protection philosophy as developed by ICRP [3] and further elaborated by IAEA [4] shall be applicable.

For all operations the following shall be taken into consideration.

- occupational exposure of individuals during waste management
- collective doses caused by waste management to workers and members of the public
- individual doses from waste management activities to persons in the critical group of the exposed population.

The radioactive waste management system shall be planned simultaneously with planning of the activity generating the waste.

Management of radioactive waste shall be carried out without undue delay and in such a manner that the resultant radiation doses to occupationally exposed persons, to critical groups and to the population as a whole are optimized and kept at acceptable levels in accordance with the basic ICRP recommendations [3] and the IAEA Basic Safety Standards [4]. As a result of the new CRP recommendations published in 1991 [5] the Agency is presently revising its Basic Safety Standards. The result of this revision might have impact on national Regulations. Doses to individuals in the general public resulting from waste management shall not be more than a fraction of the dose limit given by IAEA in its Basic

Safety Standards (some countries have used 1/10 as an acceptable fraction). The maximum value of that fraction shall be specified by the Competent Authority.

Guidelines on implementation of the Law should take into consideration emergency preparedness to take care of possible mishaps or accidents and interventions if required at the storage/disposal facilities/sites.

#### **V. Responsibility**

It is the responsibility of the waste producer to provide all necessary financial, technical and personnel resources for the safe treatment, conditioning, transport, interim storage and disposal of the waste generated, as well as to ensure the qualification of the personnel involved in the work. In some countries a central or national authority could be responsible for disposal.

The waste producer may use contractors for implementing different steps in management of the waste. The ultimate responsibility will however remain with the waste producer. (In some countries the government or a governmental organization will be responsible for disposal.)

#### **VI. Characterization, Segregation and Collection**

The waste shall be characterized and segregated in such a way as to facilitate subsequent treatment, conditioning and disposal.

The waste producer shall set up a system for suitable waste characterization which shall be approved by the Competent Authority.

The waste producer shall provide the necessary resources for the implementation of the approved waste characterization and segregation system.

Waste shall be segregated as soon as possible after generation of the waste.



The waste producer shall provide for waste collection and transport by approved methods to suitable interim storage or disposal facilities.

## **VII. Treatment and Conditioning**

The waste shall be treated in an appropriate way, as proposed by the user and approved by the Competent Authority:

- To separate the waste generated into groups which have similar characteristics and thus facilitate subsequent handling and treatment. The option of exempting and discharging waste streams should be considered.
- To reduce the volume of the waste and thus the transport, storage and disposal work, as long as it can be done within the constraints given by optimization of radiation protection and the given dose limits.
- To convert the waste into a chemical and physical form which can be handled, stored or disposed of safely and conveniently.

The treatment method shall be adapted to the aim of the treatment, the subsequent conditioning and disposal methods, the technical and economic resources as well as the personnel qualifications.

Conditioning of the waste shall be done with methods giving products compatible with the subsequent transport, storage and disposal methods. Only such methods which are in accordance with the national policy shall be used. The conditioned waste form should meet with acceptance criteria laid out by the Competent Authority for interim storage, transport and disposal.

## **VIII. Transport**

All transport of radioactive waste shall be carried out in accordance with the relevant national and international transport regulations based on the IAEA Safety Standards "Regulations for the

Safe Transport of Radioactive Materials" [6]. These regulations do not apply within establishments where the radioactive waste is generated, used or stored. The Competent Authority may give rules for transport within the establishment.

#### **IX. Labelling and Marking**

All radioactive waste shall be labelled and marked in such a way that the origin of the waste, its radionuclides and its activity content can be identified during the entire interim storage period. For waste packages containing long lived radionuclides it may be desirable to have markings which would facilitate identification of waste packages even for some time after disposal, if a decision for retrieval of some waste should later be considered.

#### **X. Storage**

All radioactive waste awaiting further treatment or disposal shall be stored under appropriate and controlled conditions. Separated interim storage facilities shall be used for unconditioned and conditioned waste. Supervision shall be carried out to the extent deemed necessary by the Competent Authority.

Interim storage of unconditioned radioactive wastes shall be as short as possible and shall not exceed 5 years. During that time, all wastes shall be conditioned (or disposed of as exempted wastes) and transferred to a special waste storage facility. Such a special waste storage may either be a central storage or a local storage of high quality which can guarantee the long-term stability required.

The storage shall be constructed in such a way and operated under such conditions that the waste does not deteriorate during storage to the extent that subsequent safe handling, transport and disposal is endangered.

The waste producer shall provide for the necessary storage facilities complying with the requirements prescribed by the Competent Authority.

## **XI. Disposal**

Disposal of waste shall be done in such a way that compliance with the general radiation protection principles are achieved. This includes compliance with the ALARA principle.

Disposal options shall be chosen in conformity with the national waste management policy.

Potential disposal options are:

- o release to the atmosphere
- o discharge to the sewage system
- o disposal on normal municipal landfill
- o disposal in shallow land disposal sites intended for radioactive waste

In special cases, the Competent Authority may demand disposal in deep geological repositories in order to comply with long-term radiological protection requirements.

## **XII. 'Exempting' Waste from Regulatory Control**

The Competent Authority may 'exempt' treatment, conditioning, storage or disposal of radioactive waste from licensing and further control under the law if the wastes have such activity concentration and total activity that the waste presents insignificant radiological hazard.

The Competent Authority may exempt wastes from further control for discharge into the sewage system, released to the atmosphere, disposal on a municipal landfill, or reuse. The basic principles for exempting radiation sources and practices from regulatory control are given in IAEA Safety Series No. 89 [7].

### **XIII. Documentation and Reporting**

The licence holder shall keep documentation to the extent prescribed by the Competent Authority. The documentation should comprise at least:

- Information on what has been purchased/produced
- Up-to-date information on what is in use
- Up-to-date information on what is in storage as useful material
- Up-to-date information on what is in storage as waste
- Up-to-date information on what has been disposed of
  - into the atmosphere
  - into the sewage systemor sent for disposal
  - in landfill or
  - in special repositories

The licence holder shall give regular reports to the Competent Authority to the extent prescribed. At least annual reports of disposed radioactive material and immediate reports on accidents or incidents that have, or may have, resulted in release of radioactive material shall be made.

Besides the documentation kept by the licence holder, the Competent Authority shall keep a national register of such sealed sources which, if not properly handled, can give rise to serious health effects. The Competent Authority shall give details on what is to be included in the national register and what reporting procedures are to be used.

### **XIV. Monitoring**

All waste to be disposed of must be measured and monitored to guarantee compliance with the limits relevant to the disposal route used.

The waste producer must have instruments or equipment capable of measuring the relevant limits applicable to the waste generated.

#### **XV. Emergency Preparedness**

All licence holders handling radioactive material shall establish an emergency preparedness plan specific to the needs of their particular establishment or operations. The plan shall also, when appropriate, include provisions for unplanned events occurring outside the normal working area; for example during transport.

For users of small amounts of radioactive material, there may be no need for special emergency preparedness outside what is needed for normal radiation protection purposes.

#### **XVI. Quality Assurance**

The waste producer shall establish working rules and control measures, such as to minimize the risk of unintentional discharge of waste to the atmosphere or the sewage system or of disposal to municipal landfills, above the limits set by the Competent Authority.

The waste producer shall establish working rules and control measures, such as to ensure that waste packages to be sent for storage or disposal as radioactive waste, are in accordance with the given information (activity content, waste form, quality of waste package etc).

**Annex I**  
**APPLICATION FOR LICENCE**

Before work with radionuclides is started or radionuclides are imported, and before any other activity needing a licence is initiated, an application shall be forwarded to the Competent Authority by the individual or legal person responsible for the waste, import or other activity. Even if it may not be necessary, it is convenient and practical to use standard application forms to ensure that all relevant information is included. Different standard forms may be used for different applications.

Applications shall contain at least the following information:

- Name and address of the natural or legal (company, hospital, research institute, etc.) person responsible for the application and for the work
- Name, position and qualifications of the person with appropriate authority suggested for co-ordinating purchase and stock of radioactive materials and the disposal of wastes.
- Description of the work to be carried out in terms used in the legislation (for instance import, sale and transport or waste management and disposal)
- Quantification of the radionuclides

**Examples:**

- (1)  $^3\text{H}$ ,  $^{14}\text{C}$ ,  $^{32}\text{P}$ ,  $^{125}\text{I}$  in the form of labelled compounds to be used in biological research. Estimated use is not more than 1 MBq per year of  $^{14}\text{C}$  and 1 GBq of each of the others.
  - (2) 1 TBq of  $^{60}\text{Co}$  as a sealed source in a GAMMAMAT TI to be used for gamma radiography.
- Description of any apparatus containing sealed sources such as thickness gauges, level gauges or radiographic equipment with

copies of any test certificate for the apparatus of above items (certificates of approval in other countries may also be accepted). These can normally be supplied by the manufacturer. It is strongly recommended to use only apparatus or equipment which has been tested and approved for safe performance. Such testing is essential.

- For sealed sources the test certificates should show that they meet with ISO or equivalent standards.
- Description of any laboratory and special equipment to be used. Enclosure of drawings may be sufficient.
- Number of persons to be involved.
- Instruments available for measuring dose rates and contamination levels, and contamination control measures.
- Personnel dosimetry procedures.
- Description of documentation and record keeping.
- Description of storage facilities for the radionuclides and the radioactive wastes preferably supplemented by drawings.
- Description of the proposed waste management system, including disposal.

When buying sealed radiation sources, especially when containing radionuclides with long half-lives, it is recommended that the purchase contract include provisions for the return of the source to the supplier once it is spent. This is of special importance when large sources are used, for example, in medical radiotherapy, gamma radiography and irradiation facilities.

## REFERENCES TO ATTACHMENTS

- [1] INTERNATIONAL ATOMIC ENERGY AGENCY, Radioactive Waste Management Glossary, IAEA-TECDOC-447, IAEA, Vienna (1988).
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- [3] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Recommendations of the International Commission on Radiological Protection, Publication 26, Annals of the ICRP 1 3, Pergamon Press, Oxford and New York (1977).
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY, Basic Safety Standards for Radiation Protection, Safety Series No.9, 1982 Edition, IAEA, Vienna (1982).
- [5] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 1990 Recommendations of the International Commission on Radiological Protection, Publication 60, Pergamon Press, Oxford and New York (1991).
- [6] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 1985 Edition (As Amended 1990), Safety Series No.6, IAEA, Vienna (1990).
- [7] INTERNATIONAL ATOMIC ENERGY AGENCY, Principles for the Exemption of Radiation Sources and Practices from Regulatory Control, Safety Series No.89, IAEA, Vienna (1988).



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