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Management of radioactive waste from the use of radionuclides in medicine

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MANAGEMENT OF RADIOACTIVE WASTE FROM THE USE OF RADIONUCLIDES IN MEDICINE

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FOREWORD

The use of radionuclides in medicine is a well established field. The favourable properties of some radionuclides, their availability on the market and acceptable cost allow a broad application of different radionuclides in modern medicine both for diagnostic and therapeutic purposes. Despite the introduction of other medical procedures that do not involve exposure to ionizing radiation, the use of sealed radiation sources and unsealed radionuclides continues to increase each year and the demand for these is growing both in industrialized and developing countries. The growing application of radionuclides results in an increased demand for efficient treatment and disposal of the associated radioactive waste. This is occurring in a climate of reduced radioactive waste generation, increasing costs of disposal and decreasing availability of disposal options, even in industrialized countries.

Recognizing the importance of the waste management issue associated with the application of different radionuclides and radiation sources in modern medicine, the IAEA initiated this publication to provide Member States with available information on the practical approaches for management of medical radioactive wastes.

Preparation of this report was accomplished through three consultants meetings and an Advisory Group meeting. The final report was prepared by consultants and the IAEA Secretariat after review of the information, data and comments received from the Advisory Group. The IAEA would like to express its thanks to all those who took part in the preparation of the report. The IAEA officer responsible for the report was V.M. Efremenkov of the Division of Nuclear Fuel Cycle and Waste Technology.

EDITORIAL NOTE

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CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

Radioactive materials have been found to be very effective when used in a variety of medical applications for diagnostic, therapeutic and research purposes. As a consequence of handling these materials, a wide range of radioactive waste is produced. The amount and types of these wastes varies depending on the scale of the medical application and the radionuclides involved. The waste that is generated during the different applications of radioisotopes in medicine or biological research is considered as biomedical radioactive waste.

Biomedical or medical radioactive waste in many cases will contain an infectious biological component from clinical, anatomical, ancillary or research sources. It may also include spent sealed sources and surplus unsealed sources. Anatomical waste arises from human and non-human sources and may include body parts, tissues, organs and fluids. Ancillary wastes are materials which may have come into contact with humans or animals and which may be contaminated with radioisotopes and possess other biological, chemical or physical hazards. Wastes from research and education activities may include by-products of radiolabelling experiments.

The overall goal of biomedical radioactive waste management is to minimize the hazards posed by the waste prior to discharge or disposal. This includes consideration of the radioactive, biological, chemical and physical hazards associated with the waste. When planning for the handling of radioisotopes in medical or health care facilities, it is important to design an effective system for the overall management of the biomedical radioactive waste. This includes all steps or activities involved in the management of radioactive waste from its generation to ultimate presentation for discharge or disposal.

1.2. OBJECTIVE

The main objective of this publication is to review the different options and provide practical guidance on the management of biomedical radioactive waste that may arise in health care facilities, clinics, laboratories and other associated medical institutions. It outlines the advanced practices used in different facilities around the world that handle radionuclides for biomedical applications and therefore deal with management of the associated waste.

Biomedical radioactive waste management includes handling, packaging, treatment, conditioning, storage, transportation and disposal of the radioactive waste that is produced in medical facilities.

When radioisotopes are to be used in a biomedical facility, proper consideration should be given to the design of the facility to ensure safe use of the material in accordance with the requirements of the regulatory organizations. Such consideration should include planning for processing, storage and disposal of all generated radioactive waste.

While this publication is directed primarily to developing Member States, it also reflects the practices applied in countries with extensive nuclear programmes. Therefore this publication should be useful for any biomedical establishment dealing with medical applications of radioisotopes and consequently with the wastes associated with such applications.

1.3. SCOPE

This publication addresses aspects of management of biomedical radioactive waste from its generation to final disposal or release. Section 2 describes sources and characteristics of biomedical radioactive waste. Section 3 gives an overall assessment of the planning methods used in radioactive waste management at medical premises. Collection, segregation and packaging of biomedical radioactive waste is covered in Section 4. Section 5 details the requirements for storage and transportation of biomedical radioactive waste. Section 6 provides information on the management of liquid (aqueous and organic), solid and gaseous biomedical radioactive wastes at both an on-site and at a centralized waste processing facility. Options on handling spent sealed radiation sources used in medicine are outlined in Section 7. Section 8 provides information on radioactive waste clearance levels.

This publication also provides, in Section 9, the general principles applied to quality assurance and quality control of biomedical radioactive waste management, and concise recommendations in Section 10.

2. SOURCES AND CHARACTERISTICS OF BIOMEDICAL RADIOACTIVE WASTE

2.1. CHARACTERISTICS OF UNSEALED RADIONUCLIDES USED IN MEDICINE

Numerous radionuclides are used in both unsealed and sealed forms during different biomedical procedures. A list of the radionuclides used as unsealed sources and their applications may be found in Table I.

2.1.1. Diagnostic

The use of radionuclides for diagnostic purposes has both “in vitro” and “in vivo” applications. In vitro means studies performed on human biological samples outside of the human body while in vivo refers to dynamic function studies within the human body. In vitro applications typically involve kBq activities of aqueous-based radionuclides being utilized to measure levels of drugs or hormones in biomedical samples. Typical radionuclides include ^{125}I, ^{57}Co ^{58}Co and ^{14}C.

By far the greatest diagnostic application of radionuclides in medicine is in vivo investigation of body function using gamma camera imaging. Many in vivo radiopharmaceuticals are prepared by diluting a pharmaceutical with ^{99m}Tc, which is eluted from a ^{99m}Tc generator. Radionuclides are also administered in vivo to act as tracers in monitoring body functions. The usual range of administered doses for technetium radiopharmaceuticals is 40–800 MBq, with lower doses administered for paediatric patients.

TABLE I. RADIONUCLIDES USED IN MEDICINE AND BIOLOGICAL RESEARCH IN UNSEALED FORM

Radionuclide	Half-life	Principle application	Typical quantity per application	Waste characteristics
^{3}H	12.3 a	Radiolabelling Clinical measurement Biological research Organic synthesis	Up to 50 GBq	Solvents, solid liquid
^{13}N	10 m	Positron emission tomography	Up to 2 GBq	Solid, liquid
^{11}C	20.4 m	Positron emission tomography	Up to 2 GBq	Solid, liquid
^{14}C	5730 a	Medical diagnosis Biological research Labeling	Less than 1 MBq Up to 50 GBq Up to 50 GBq	(Exhaled CO_2) Solid, liquid Solvent
^{15}O	122 s	Positron emission tomography	Up to 500 MBq	Solid, liquid
^{18}F	1.8 h	Position emission tomography	Up to 500 MBq	Solid, liquid
^{22}Na	2.605a	Medical diagnosis	Up to 1MBq	Solid, liquid
^{24}Na	15.0 h	Biological research	Up to 5 GBq	Liquid effluent
^{32}P ^{33}P	14.3 d 25.4 d	Clinical therapy Biological research	Up to 200 MBq Up to 50 MBq	Solid, liquid effluent
^{35}S	87.4 d	Medical and biological research	Up to 5 GBq	Solid, liquid effluent
^{36}Cl	3.01×10^{5} a	Biological research	Up to 5 MBq	Gaseous, solid, liquid
^{38}K ^{42}K ^{43}K	7.6 m 12.4 h 22.2 h	Positron emission tomography Clinical measurement Clinical measurement	Up to 1 GBq Up to 5 MBq Up to 5 MBq	Solid, liquid Solid, liquid Solid, liquid
^{45}Ca ^{45}Ca	163 d 4.54 d	Biological research Medical diagnosis	Up to 100 MBq Up to 100 MBq	Mainly solid, some liquid
^{46}Sc	83.8 d	Medical and biological research	Up to 500 MBq	Solid, liquid
^{51}Cr	27.7 d	Clinical measurements Biological research	Up to 5 MBq Up to 100 MBq	Solid Mainly liquid effluent
^{57}Co ^{58}Co	271.7 d 70.8 d	Clinical measurements Biological research	Up to 50 MBq Up to 5 MBq	Solid, liquid effluent
^{59}Fe	44.5 d	Clinical measurements Biological research	Up to 50 MBq	Solid, mainly liquid effluent
^{67}Ga	3.3 d	Clinical measurements	Up to 200 GBq	Solid, liquid effluent
^{68}Ga	68.2 m	Positron emission tomography	Up to 2 GBq	Solid, liquid
^{67}Cu	2.6 d	Clinical therapy Monoclonal antibodies	Up to 1 GBq	Solid, liquid
^{75}Se	119.78 d	Clinical measurements	Up to 10 MBq	Solid, liquid
^{75}Br ^{76}Br	98 m 16.2 h	Medical diagnosis Medical diagnosis		Solid, liquid Solid, liquid
^{77}Br	57 h	Clinical measurement	Up to 5 MBq	Solid, liquid
^{81m}Kr	13.3 s	Lung ventilation studies	Up to 6 GBq	Gaseous
^{82}Rb ^{82m}Rb	76 s 6.2 h	Positron emission tomography Clinical measurement		Solid, liquid Solid, liquid
^{86}Rb	18.7 d	Medical and biological research	Up to 50 MBq	Solid, liquid

TABLE I (cont.)

^{85}Sr	64.8 d	Medical diagnosis/research	Up to 50 MBq	Solid, liquid
^{89}Sr	50.5 d	Clinical therapy	Up to 300 MBq	Solid, liquid
^{90}Y	2.7 d	Clinical therapy Medical and biological research	Up to 300 MBq	Solid, liquid
^{95}Nb	35.0 d	Medical and biological research	Up to 50 MBq	Solid, liquid
^{99m}Tc	6.0 h	Clinical measurements Biological research Nuclide generators	Up to 100 GBq	Solid, liquid
^{111}In	2.8 d	Clinical measurements Biological research	Up to 50 MBq	Solid, liquid
^{123}I ^{124}I ^{125}I ^{131}I	13.2 h 4.2 d 60.1 d 8.0 d	Medical and biological research Medical diagnosis/research Clinical measurements Clinical therapy	Up to 500 MBq Up to 11.1 GBq	Solid, liquid Occasionally vapor
^{113}Sn	155.0 d	Medical and biological research	Up to 50 GBq	Solid, liquid
^{127}Xe	36.4 d	Medical diagnosis	Up to 200 MBq	Gaseous, solid
^{133}Xe	5.3 d	Clinical measurements	Up to 400 MBq	Gaseous, solid
^{141}Ce	32.5 d	Medical research	Up to 50 MBq	Solid, liquid
^{153}Sm	47 h	Clinical therapy	Up to 8 GBq	Solid, liquid
^{169}Er	9.3 d	Clinical therapy, palliative treatment	Up to 500 MBq	Solid, liquid
^{186}Re	3.8 d	Clinical therapy, palliative treatment	Up to 500 MBq	Solid liquid
^{188}Re	17 h	Clinical therapy	Up to 500 MBq	Solid, liquid
^{198}Au	2.7 d	Clinical measurements, therapy	Up to 500 MBq	Solid, liquid
^{201}Tl	3.0 d	Clinical measurements	Up to 200 MBq	Solid, liquid
^{203}Hg	46.6 d	Biological research	Up to 5 MBq	Solid, liquid

Other common diagnostic imaging radionuclides include: ^{67}Ga, ^{111}In, ^{201}Tl, ^{123}I and ^{131}I. These radionuclides are usually administered at activity levels in the range of 40–400 MBq for imaging purposes.

Some radionuclides are also used to label human blood components to act as tracers for sites of blood loss or sites of infection. This typically involves removing a blood sample from the patient, radiolabelling the blood and re-injection. Examples of the radionuclides used include ^{99m}Tc, ^{111}In, ^{51}Cr, ^{59}Fe and ^{125}I. The actual activity that may be re-injected is usually in the range of a few MBq to a maximum of 200 MBq, with the highest activity typically used for ^{99m}Tc.

Radioactive gases and aerosols are used for diagnostic purposes during lung ventilation imaging. This involves the use of ^{81m}Kr (up to 6 GBq administration per patient), ^{133}Xe (up to 400 MBq) and ^{99m}Tc-diethyl tetra penta acetic acid (DTPA) aerosol inhalation (up to 80 MBq inhalation activity).

2.1.2. Therapeutic

Therapeutic applications of radionuclides in medicine utilize a number of unsealed sources in much higher activities than those used for diagnosis. Iodine-131 is widely used for treatment of thyrotoxicosis and for ablation of the thyroid tissue or metastases during cancer treatment. Individual patient doses are typically in the range of 200 MBq — 11 GBq. The ^{131}I used for therapeutic purposes may be provided in three physical forms — liquid sodium iodide for dispensing as multiple individual patient doses for oral administration, individual powder filled gelatin capsules for oral administration or sterile sodium iodide solution for injection. Injections are normally only administered where there may be a problem with oral administration.

Use of other therapeutic unsealed radionuclides usually involves venous injection of a sterile, undiluted solution of the radionuclide, e.g. ^{89}Sr or ^{32}P. Strontium is typically used in therapy for the management of pain associated with bone metastases. Administered doses are usually several hundred MBq. Yttrium-90 is typically injected into the joints of a patient, e.g. knee, as a silicate colloidal solution, with administered activity levels of about 200 MBq per injection.

Some radionuclides used in therapeutic applications are diluted prior to administration. This practice may increase the volume of wastes requiring further management. For example, therapeutic administration of ^{131}I-MIBG (meta-iodo benzyl-guanidine) is usually diluted with sterile isotonic saline and is intravenously administered slowly over a period of up to an hour or more using a pump system. This results in the generation of additional solid radioactive waste, such as disposable plastics.

2.1.3. Research

A wide range of unsealed radionuclides are used for research purposes both in health care biological research centers and pharmaceutical development facilities [1]. Isotopes such as ^{3}H, ^{35}S, ^{32}P and ^{33}P are widely used for DNA sequencing in research.

The range of radionuclides used in biomedical research is much wider than the number of radionuclides used for in vitro and in vivo diagnostic/therapeutic purposes. The reason for this is that a large number of new uses of radionuclides are often evaluated for several years in animal studies at pharmaceutical development establishments prior to being approved for use. This is necessary to verify that the product is safe for human administration.

Wastes generated as part of drug evaluation research may often be stored frozen for prolonged periods (2–5 years) on the user's premises whilst the drug regulatory organizations evaluate the results of clinical trials. The final approval of the drug for use can involve the sudden requirement for disposal of large volumes of frozen wastes, including animal carcasses, tissues, organs, blood products, urine and faeces and by-products of radiolabelling experiments.

The use of radionuclides such as ^{3}H and ^{14}C in GBq quantities for organic synthesis is not uncommon in pharmaceutical research, resulting in low volume, high activity waste for management and disposal. Often the waste generated from biomedical research is more difficult to control due to transient workers on research grants or project work by students.

Research work typically involves the use of animals, hence wastes will include animal tissues and carcasses, contaminated bedding material and excrement. Often the wastes from these sources are more difficult to manage and to quantify.

2.2. CHARACTERISTICS OF RADIOACTIVE SEALED SOURCES USED IN MEDICINE

2.2.1. Diagnostic

Sealed radiation sources may be used for the following diagnostic purposes:

— bone densitometry,
— anatomical marking,
— calibration and reference standards.

Density scanners for bone mineral determination are one example of a diagnostic application of radiation sources in medicine. Typical sources used for these purposes are ^{241}Am, ^{153}Gd or ^{125}I at activity levels of up to several GBq. At the end of their useful life, these spent radiation sources should be sent to a centralized facility for treatment and disposal.

Since anatomical markers, calibration sources and reference standards may have small dimensions and low activity, special care should be taken to ensure that they are not lost in use, e.g. accidentally discarded with the normal waste or misplaced during medical applications.

2.2.2. Therapeutic

A number of different radionuclides are used in the form of sealed sources for clinical treatment during manual brachytherapy, remote after-loading brachytherapy, teletherapy, blood irradiation and other purposes. Since sources of rather high activity may be involved, attention should be paid to proper shielding, storage and security as soon as the sources are taken into use.

Sealed sources are used in a wide range of activities for therapeutic purposes. Many are directly implanted during oncology treatments or applied to a patient, e.g. ^{106}Ru eye plaques and implants of ^{192}Ir, ^{137}Cs and ^{198}Au. Sealed sources are also now being used in vascular treatments for stenosis as a complement to angioplasty during catheterization. Sources include both beta and gamma emitters such as ^{192}Ir and ^{89}Sr.

Larger sealed sources such as ^{60}Co are used in teletherapy heads for beam treatments of malignant conditions. Cobalt-60 is also used in gamma knife surgery where approximately 200 sources are focused on a very small portion of the patients head. These applications may involve activities of up to several hundred TBq.

Some therapeutic sealed sources are not used directly for human therapy, e.g. the TBq sources of ^{137}Cs or ^{60}Co used in blood cell irradiators.

Although radium sources are no longer used in good medical practice, spent sources may still be stored and require treatment and disposal. Specific precautionary measures should

be applied to their storage because such sources will eventually leak. A detailed description of how to treat them is presented in previous IAEA publications [2, 3].

2.2.3. Research

Sealed radioactive sources may also be used in research and teaching/training establishments. These may involve small sealed calibration sources used for gamma and liquid scintillation counting and ^{63}Ni sources for gas chromatography. Some establishments may also use much higher activity sealed sources in irradiators such as ^{137}Cs or ^{60}Co sources.

A list of radionuclides used in medicine and medical research as sealed sources is presented in Table II.

TABLE II. SEALED SOURCES USED IN MEDICINE AND MEDICAL RESEARCH

Application	Radioanuclide	Half-life	Source activity	Comments
Bone densitometry	^{241}Am ^{153}Gd ^{125}I	433.0 a 244.0 d 60.1 d	1–10 GBq 1–40 GBq 1–10 GBq	Mobile units
Manual brachytherapy	^{198}Au ^{137}Cs ^{226}Ra ^{60}Co ^{90}Sr ^{103}Pd ^{125}I ^{192}Ir ^{106}Ru ^{90}Y	2.7 d 30.0 a 1600 a 5.3 a 29.1 a 17.0 a 60.1 d 74.0 d 1.01 a 2.7 d	50–500 MBq 30–300 MBq 50–500 MBq 50–1500 MBq 50–1500 MBq 50–1500 MBq 200–1500 MBq 5–100 MBq 10–20 MBq 50–500 MBq	Small portable sources
Vascular brachytherapy	^{32}P ^{89}Sr ^{192}Ir	14.3 d 50.5 d 74 d	200 MBq 150 MBq 0.1–1 TBq	Catheterization
Remote after loading brachytherapy	^{137}Cs ^{192}Ir	30.0 a 74.0 d	0.03–10 MBq 0.1–200 TBq	Mobile units
Teletherapy	^{60}Co ^{137}Cs	5.3 a 30.0 a	50–1000 TBq 500 TBq	Fixed installations
Whole blood irradiation	^{137}Cs ^{60}Co	30.0 a 5.3 a	2–100 TBq 50–1000 TBq	Fixed installations
Research	^{60}Co ^{137}Cs	5.3 a 30.0 a	Up to 750 TBq Up to 13 TBq	Fixed installations
Calibration sources Anatomical markers Sources as standards in instruments	^{63}Ni ^{137}Cs ^{57}Co ^{226}Ra* ^{147}Pm ^{36}Cl ^{129}I	96 a 30.0 a 271.7 d 1.6×10^{3} a 2.62 a 3.01×10^{5} a 1.57×10^{7} a	<4 MBq <4 MBq Up to 400 MBq <10 MBq <4 MBq <4 MBq <4 MBq	Fixed installations in instruments or mobile sources
Gamma radiosurgery knife	^{60}Co	5.3 a	Up to 220 TBq	Skull cap

* Radium sources are no longer used for therapeutic treatment but exist as spent sources in some hospitals.

2.3. TYPES OF BIOMEDICAL RADIOACTIVE WASTE

2.3.1. General

The use of a wide range of radionuclides in medicine and medical research leads to the generation of waste, which requires a comprehensive management system. In many instances, the potential additional hazards, either from the chemical, biological or physical properties are greater than the radiological hazard due to the presence of radionuclide contamination.

The following is a non-exhaustive list of the types of radioactive waste that may occur as a result of the use of radionuclides in medicine:

— surplus solutions of radionuclides from diagnostic, therapeutic and research applications which are likely to be sterile;
— aqueous based solutions containing low levels of radionuclides, e.g. from washing of apparatus;
— organic based solutions which may or may not be miscible with water, e.g. liquid scintillation counting residues and residues from organic synthesis;
— excreta from patients administered with radionuclides for diagnostic or therapeutic purposes;
— anatomical wastes, e.g. body parts, tissues, organs and fluids;
— spent radionuclide generators or spent radioactive solutions, such as those from radiopharmaceutical preparation;
— miscellaneous solid and semi-solid, wet wastes which may or may not be suitable for landfill or combustion, e.g. incontinence pads soiled with excreta, absorbed liquids;
— resin columns, matrix gels and chromatography plates from medical diagnosis and research;
— food waste from patients administered with radionuclides for therapeutic purposes, e.g. ^{131}I ablation therapy;
— miscellaneous solid, dry wastes which are suitable for compaction, combustion or shredding, e.g. gloves, paper tissues;
— miscellaneous solid, dry wastes which may be not suitable for compaction, combustion or shredding, e.g. furniture and equipment parts;
— miscellaneous wastes which pose a puncture hazard, e.g. needles, broken glass, vials;
— waste from spills, decontamination and decommissioning procedures, e.g. liquids absorbed on matrix, mops, tissues;
— filters used in equipment, e.g. charcoal traps, fume hood filters;
— fragments from sources used in brachytherapy, e.g. cut lengths of iridium wire;
— ancillary wastes, e.g. materials which may have come into contact with humans or animals;
— spent sealed sources.

2.3.2. Liquid waste

Liquid radioactive waste includes contaminated water and effluent, waste arising from chemical processing and decontamination solutions, solvents, blood or body fluids, discarded liquid radiopharmaceuticals, wound or oral discharges, urine, chemotherapy agents, small quantities of contaminated oils and scintillation fluids. Waste that includes both radioactivity and a hazardous chemical component is usually referred to as a mixed waste.

2.3.3. Gaseous waste

Xenon-133 and ^{81m}Kr are used in diagnostic imaging for assessment of regional lung ventilation. Since they are noble gases, they are difficult to treat and are often released to the atmosphere through an exhaust system. It is essential to ensure that there is no possibility of re-entry of the released gases back into the building through open windows or ventilation system.

2.3.4. Solid waste

At health care, medical and research facilities, solid waste is generated in the form of paper and plastic, animal carcasses, contaminated materials, discarded radiopharmaceutical containers, bandages, contaminated equipment or organs and tissues. Solid waste is typically classified as combustible/non-combustible and compactible/non-compactible waste. It generally contains a relatively low level of radioactivity when compared to liquid wastes. Solid radioactive waste consists mainly of general biomedical waste, which includes protective clothing, plastic sheets and bags, gloves, masks, filters, overshoes, paper wipes, towels, metal and glass, hand tools and discarded equipment.

2.3.5. Spent sealed sources

Sealed sources at the end of their useful clinical life are categorized as waste which needs to be properly conditioned and disposed of. Spent sources could be divided into the following categories:

— Sources with half-life <100 days, with high activity content such as ^{192}Ir (200–1500 MBq);
— Sources of low activity used for calibration and as standards;
— Sources with a potential emanation and contamination hazard. Special security and radiological precautions need to be taken for the handling and the storage of spent radium sources and sources known to be leaking;
— Sources with half-life >100 days, with low or high activity.

2.3.6. Decommissioning waste

Use of accelerators in medicine may also produce radioactive waste, specifically during decommissioning of these facilities. The use of accelerators can create an activation problem of surrounding materials, particularly with neutrons of energy higher than 10 MeV.

Linear accelerators

During decommissioning of linear accelerators used in oncology centers, the problem is essentially limited to the collimating heads of the machines. The activation products increase when the machine is used at higher energies and mainly involves production of ^{60}Co, ^{57}Co and ^{181}W. Activation product levels up to 1 kBq/g for cobalt and 26 kBq/g for wolfram have been measured at the end of the useful life of a 20 MeV accelerator after dismantling. The activation of concrete in the biological shield or base of a linear accelerator used for medical purposes is very low and does not result in the production of radioactive waste.

Historically, depleted uranium was used for the shielding material in linear accelerators and for other sources. Such wastes must be considered as part of an overall radioactive waste management strategy during decommissioning.

In recent years, manufacturers have become increasingly concerned with the problem of activation and the resultant waste management problems. They have started preventative action by more appropriate selection of materials and technology at the time of equipment manufacture.

Cyclotrons

The use of cyclotrons in isotope production for patient diagnosis and treatment can lead to more activation and waste problems during decommissioning than linear accelerators. The metal machine parts and infrastructures of beam lines and collimators should be considered as radioactive waste during the decommissioning planning process. The activation of the concrete biological shielding around cyclotrons could also yield waste problems such as with machines used for ^{201}Tl production with external targets. The major element of concern is Europium which occurs in sand used for concrete.

Activation in concrete has been measured up to 70 cm depth. The iron reinforcement bars in concrete may be activated with ^{60}Co to more than 10 kBq/kg. Therefore the use of iron and scrap metals in concrete shielding around cyclotrons is no longer recommended. A less important tritium activation can occur of more than 10 Bq/g.

Cyclotrons could thus present a decommissioning problem and generate a considerable volume of metal and concrete waste. Where practicable, decommissioning should be deferred for decay until clearance levels are met, in order to reduce or prevent waste management costs.

Minimization of waste during decommissioning should be considered at the design and construction stage, when it is possible to select the most appropriate construction materials. Incorporation of materials to absorb neutrons could be useful. Removable concrete blocks could be used for the inner parts of shielding walls to reduce dismantling problems during decommissioning.

However, most of decommissioning wastes are not considered as biomedical. Consideration for management of these wastes is given in Ref. [4].

2.4. NON-RADIOLOGICAL HAZARDS

The non-radiological hazards of biomedical radioactive waste can be divided into the following categories:

— physical hazards,
— chemical hazards,
— biological/infectious hazards,
— flammable/explosive hazards.

2.4.1. Physical hazards

Physical hazards include the possibility of cuts and puncture injuries such as those from needles, broken glass, scalpel blades or blood lancets (sharps). Physical hazards will also include injuries sustained as a result of manual handling of heavy objects such as shielding, containers, radioactive patients, etc.

2.4.2. Chemical hazards

Chemical hazards include the potential for adverse chemical reactions or injuries which may be posed by the presence of acids, alkalis, oxidizers or oxidizable organic matter. These hazards may be associated with liquid or vapors containing dangerous chemicals. Chemical hazards may arise from the mixing of incompatible wastes.

2.4.3. Biological/infectious hazards

Any waste generated in a health care facility which is contaminated with human blood, other body fluids, or any potentially infectious material is determined as “biohazardous”.

When handling any biohazardous waste, *Universal precautions* [5] should be observed. *Universal Precautions* are an infection control concept which assures that all human blood, body fluids or other biohazardous wastes are treated as if they are infected with HIV, Hepatitis B virus or other biohazardous pathogens.

Animal carcasses and human pathological remains are also sources of biological and/or infectious hazards, and again must be handled using *Universal Precautions*.

Universal Precautions involves use of protective equipment and standard operating procedures to protect the health of the worker, patient or health care facility visitor. These precautions include:

— hand washing,
— wearing of disposable gloves,
— use of protective gowns,
— use of face masks, protective eye glasses, etc.

Staff who are routinely handling biohazardous biomedical waste should be offered appropriate immunization and testing for diseases such as hepatitis B and tuberculosis.

2.4.4. Flammable/explosive hazard

Such hazards can arise when low flash point organic scintillants (<21^{o}C) are stored. It is essential that the radioactive store has spark resistant lighting and that these wastes are securely stored in metal bins/cabinets. The radioactive store should also be adequately ventilated to prevent the buildup of fumes and a subsequent explosion hazard. The radioactive store should not be located in the vicinity of other flammable hazards such as compressed gases or highly combustible wastes.

3. ASSESSMENT AND OPTIMIZATION OF RADIOACTIVE WASTE MANAGEMENT AT HEALTH CARE ESTABLISHMENTS

Radioactive waste from the medical sector does not present a significant long term waste management problem when compared to wastes generated from nuclear fuel cycle operations. The most important characteristics of biomedical waste are its short half-life and low radiotoxicity. Biomedical waste typically contains low energy β and γ emitters and is generally of low total and specific activity. Important considerations are the volumes of waste and other hazardous properties associated with the waste such as biological and chemical risks.

An effective programme for biomedical radioactive waste management is based on the principles of waste prevention and minimization, whilst providing for the protection of personnel and the environment, consistent with the requirements of the regulatory authority. Such management should integrate all associated hazards that are found in the waste. A generic diagram detailing the basic steps in biomedical radioactive waste management is given in Fig. 1.

The basic principles of radioactive waste management are described elsewhere (see Section 6.2) and include providing for the protection of the general public and the environment [6]. The principles of waste prevention and minimization are described in Section 4.1.1.

A comprehensive waste management programme requires a thorough prior assessment to ensure that the primary focus is waste prevention and minimization whilst providing for protection from all associated hazards of the waste. This assessment will include an analysis of the total radionuclide inventory and pattern of use, waste types and amounts generated and the potential routes for disposal. This review will seek to harmonize the waste management activities of all areas within a facility.

Such an evaluation is best carried out at the planning stage of a facility allowing for the incorporation of specific features which will enhance waste management throughout the facility. In most circumstances, however, the evaluation will be carried out on an existing facility which may have individual laboratories with their own specific waste management practice and instructions. For such circumstances, harmonization of waste management activities becomes even more important. Only when all uses of radionuclides have been evaluated can it be ascertained what waste minimization practices need to be implemented and how waste management can best be organized.

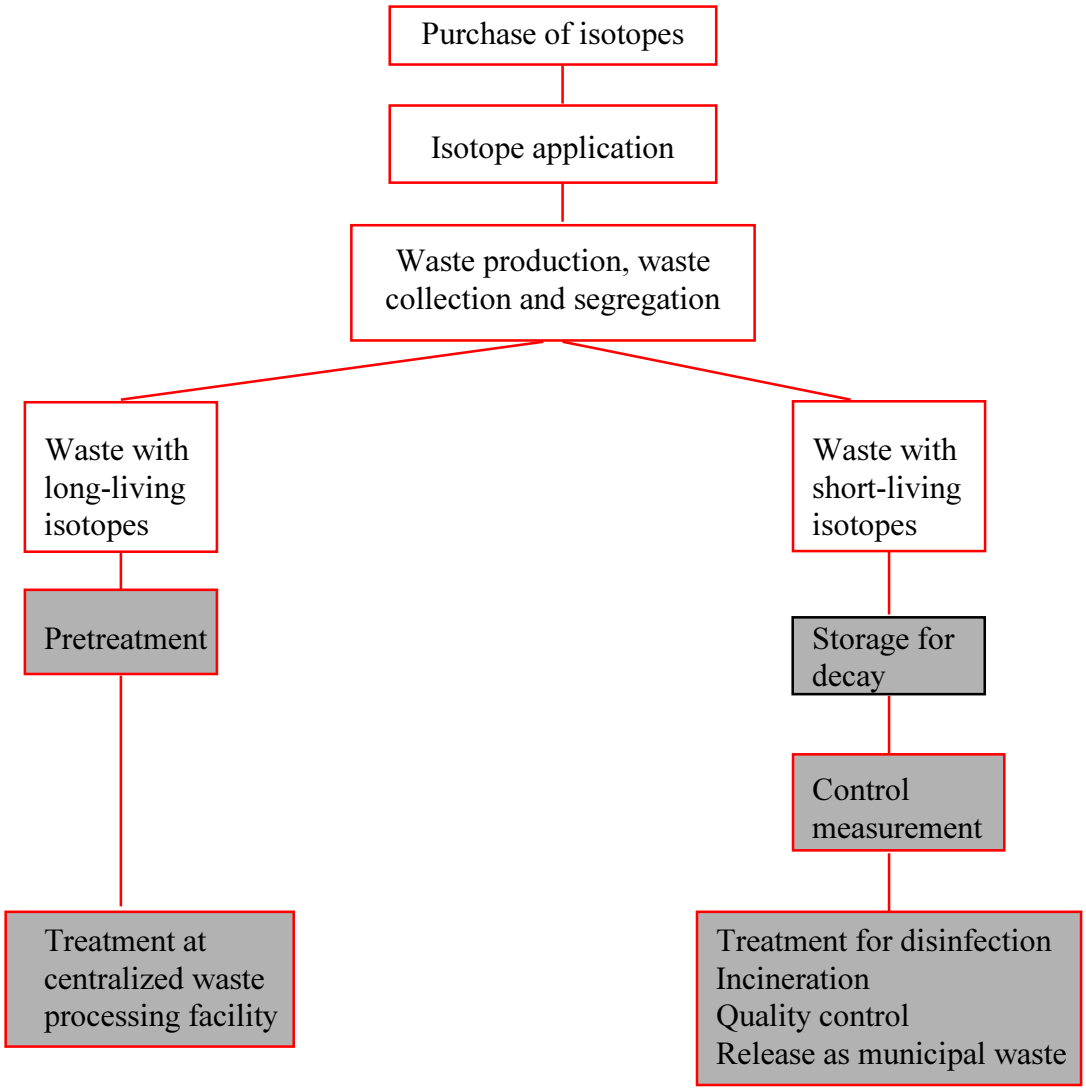


Fig. 1. Management of biomedical radioactive waste.

The radioactive waste management programme must be comprehensive and should consider all aspects, starting with radionuclide purchase through to the final clearance of waste packages from the facility to disposal or discharge. Clearance of radioactive waste from further regulatory control can only be achieved through a careful programme of waste flow control and measurement of residual radioactivity. Biomedical waste is usually best managed on-site by decay storage, with minimal transport risks and ALARA exposure levels. Since quantitative estimation of isotope activity can be difficult where waste packages contain a mixed combination of β-γ emitters, segregation at the time and place of waste production is essential.

An important component of effective waste management is the preparation of universal documented procedures. Such procedures will detail requirements for practices such as waste segregation at source and appropriate containers/receptacles for accumulation of waste. All staff should be appropriately trained in the implementation of these procedures. Responsible personnel should be identified for each stage in the waste management process, with management committing total support to the implementation of the overall waste policy.

As part of the evaluation of a waste management programme, it is necessary to collect information specific to each facility. This data will provide the basis for determining potential opportunities for further waste management optimization. The data should be recorded in a data management system allowing for follow-up of waste flows from source to final disposal, and should include:

— Data on all characteristics of the waste generated and radionuclides used within the facility;
— Reference to authorizations and details of authorized waste disposal routes;
— Organizational responsibility for the radioactive waste management programme (collection, transport, storage for decay, clearance);
— Reference to procedures that are currently in use for management of radioactive waste;
— Specifications of how the radionuclide content and activity of individual waste packages is quantified and verified;
— Data on dose rate and contamination;
— Types of packaging used for each type of medical radioactive waste;
— Data on decay storage and pretreatments of medical radioactive waste;
— Reference to quality control procedures, and if in place, audit as part of an overall quality assurance programme;
— Data to verify whether all regulatory requirements are being met;
— Certification of measurements made.

The subject of the waste management programme evaluation, quality assurance and quality control in more detail is discussed in Section 9.

Collation of data obtained by utilization of these guidelines will give an overall picture of radionuclide usage and management requirements. The data will enable a full review of current practices to be undertaken with a view to implementing an overall strategy for purchasing control of radionuclides and management of radioactive wastes.

It is essential at an early stage to co-ordinate with the on-site radiation protection supervisor(s)/advisor and seek support in taking the necessary steps. These people will have >first hand = knowledge of the working environment and be able to provide specific advice on where information can be obtained relating to any non-radiological hazards which might necessitate the continuation of the current waste segregation and management procedures. By collaboration, the practical implementation of optimization of waste management can be taken forward, with additional training of staff as required.

In some instances, modification to the radioactive storage room, or the organizational arrangements for its use, will be necessary before it would be appropriate to alter the period that waste is held on the premises to permit radioactive decay. Although these improvements may have cost implications, they can often be met by savings that will be made by decaying short half-life radionuclides (T_2 < 100 days) such that they can be disposed of at clearance levels.

The overall development of a waste management strategy is not a static process. It should be subject to periodic review, at least annually, to ensure optimization of waste management practices, e.g. by cost-benefit analysis and continued compliance with regulatory requirements. Usage of individual disposal routes, i.e. incineration, landfill, a repository for

low level radioactive waste and sewers for discharge to drain, should be reviewed when disposal routes change their pricing structure to ensure cost-effective and environmentally sound use of disposal routes, whilst maintaining full compliance with regulations governing both the radiological and non-radiological hazards that may be associated with the wastes.

4. SEGREGATION AND PACKAGING OF BIOMEDICAL RADIOACTIVE WASTE

4.1. WASTE VOLUME MANAGEMENT

An essential component of an integrated radioactive waste management system is to ensure adequate control of the activity, activity concentration, and the volume of radioactive waste. The waste management plan (Section 3) should consider the wastes produced both as a result of the original waste activity and the secondary wastes generated by the subsequent treatment and conditioning of the original waste. In all instances, this will involve implementation of waste prevention and minimization practices. However, in some countries under certain well defined circumstances it is allowed to dilute the overall radionuclide content of the waste. This is achieved by increasing the volume of very low level radioactive waste by addition of other non-radioactive wastes to comply with specific activity limits laid down by the regulatory authority.

4.1.1. Waste prevention and minimization

Waste prevention is an essential precursor of any radioactive waste management strategy. When designing experiments or planning patient diagnosis, the need to use radionuclides should always be justified and only the required quantities should be procured. In the case of medical treatments, this is done on the basis of individual benefit/risk evaluation, whereas in research, the existence of an alternative technology and the high costs of radioactive waste management are important considerations. Furthermore, the public is becoming increasingly sensitive to disposal of radioactive materials to the environment. This is of concern to the waste producing establishment, both in terms of public perception of their corporate image, and in respect of contributing to sustainable environmental and global development. Some alternatives for waste production include calorimetric or chemiluminescent assays as substitutes for radioimmunoassays, or substitution of radionuclides with shorter half-life, such that the shorter decay times will permit storage for decay and disposal at clearance levels.

Waste minimization is fundamental to any radioactive waste management strategy [7]. The objective of waste minimization is to reduce the activity and the volume of wastes for storage, treatment and disposal. Consequently the environmental impact will also be reduced, as well as the costs associated with contaminated material management.

Waste minimization can be achieved by considering the following fundamental principles:

(1) Keeping the generation of radioactive waste to the minimum practicable, in terms of both its activity and volume, through appropriate design measures, facility operation and decommissioning practices specific for medical facilities. This includes the selection

and control of materials, and the implementation of appropriate procedures. Emphasis should be placed on the segregation of different types of materials to reduce the volume of radioactive waste and to facilitate its management.

(2) Minimizing the spread of radioactive contamination, which leads to the production of radioactive waste. This should be achieved, as far as possible, by maximizing efforts of containment and minimizing the creation of secondary waste. It is desirable to use all means to prevent contamination, provided such measures are economically justified.

(3) As far as it is practicable, separating valuable materials from waste and to clear valuable materials for recycling and reuse. This principle is of limited application in the case of biomedical waste, however it may be appropriate in some circumstances, for example during decommissioning of medical irradiation facilities.

(4) Minimizing the amount of radioactive waste once it has been created through optimizing the use of available treatment technology. The volume of radioactive waste from medical facilities may be reduced by increased use of processes such as compaction, incineration, filtration, and evaporation.

In particular, practical implementation of waste minimization can be achieved by minimizing:

— the activity of the waste by using short-lived radionuclides whenever possible, which can be decayed prior to disposal;

— the volume of waste, in part by ensuring that non-essential non-radioactive materials are not taken into controlled areas, hence reducing potential cross contamination and the need for decontamination or disposal.

Reduction at source is the most effective step in achieving waste minimization. Proper design may minimize the generation of waste by several orders of magnitude. The following general features should be considered in relation to a health care facility generating radioactive waste:

(a) The most effective and reliable technology should be used, taking due account of safety requirements for radioactive and biohazardous waste control.

(b) Provision for segregation of radioactive materials from non-radioactive materials should by design be kept, out of controlled areas.

(c) The minimum quantity of radioactive materials should be procured for each application, with subsequent usage supported by written procedures.

(d) Containment and packaging of radioactive materials should be adequate to retain the contents without resulting in unnecessary volumes of packaging for subsequent disposal.

(e) Decontamination of areas and articles and control of the spread of contamination should be assured when persons or articles leave controlled areas. Adequate control should be maintained to avoid cross-contamination or excessive production of radioactive waste.

(f) Experiments and clinical trials should involve the minimal use of human subjects and animals and be consistent with sound medical practice for obtaining scientifically sound data.

(g) Detailed procedures to minimize production of ancillary and secondary waste resultant from both biohazardous waste and radioactive decontamination procedures should be drafted and staff trained in their implementation.

(h) Wherever possible, spent sealed sources should be returned to the vendor, using the original packaging material when practicable.

As mentioned previously, for most purposes, the recycling or reuse of available materials from waste arising in the medical sector is not practicable due to the potential for an infection hazard. One example where this is possible is the reuse of the single-trip Type A packaging in which radionuclides were received from the vendor. By unpacking the contents outside of controlled areas, the packaging can be kept free of biological and radiological contamination and can be reused as excepted packaging for future radionuclide transport purposes.

4.1.2. Dilution

Dilution can be considered as the release of radionuclides to the environment (gases or liquids) while maintaining proper clearance levels (Section 8.1) or the addition of non-radioactive waste to decrease specific activity levels.

In many countries, the practice of increasing the volume of radioactive waste prior to disposal to achieve compliance with a maximum specific activity limit per unit volume is either not practiced or specifically prohibited. However, in some countries, the regulatory process authorizes the practice for disposal of wastes to landfill or via a municipal incinerator which may be exempt from further regulatory control. It is a common practice in some countries for non-biologically hazardous, very low level radioactive waste to be subject to addition of other non-radioactive waste to increase the volume to bring the overall consignment within a specific activity limit. In India this waste is subject to a restriction of a maximum of 500kBq/0.1m^3, with a single item limit of 50 kBq whereas in the UK, the limits are 400 kBq/0.1 m^3, with a single item limit of 40 kBq. The above limits are increased by a factor of ten where the radionuclide is tritium. Such practices can be carried out only when authorized by the regulatory authority, having due consideration for the environmental impact.

The clearance levels proposed by the IAEA [8] will be developed and implemented by Member States following guidance put forward in the revised European Union (EU) Basic Safety Standards Directive [9] in terms of quantities and concentrations of activity per unit mass (kBq/kg). This guidance will be nuclide specific and irrespective of the physical form, and should permit disposals of low quantities to be made without prior authorization, reporting or licensing. Further details of clearance levels for radionuclides from regulatory control is given in section 8.1.

4.2. PRINCIPLES FOR COLLECTION AND SEGREGATION OF WASTE

To minimize waste arisings and optimize use of available radioactive waste disposal routes, waste should be accumulated and segregated with due regard to the future steps used in the waste management process. In contrast to other nuclear applications, the use of radionuclides in medicine nearly always involves only one radionuclide being used per procedure. This makes segregation of waste by individual radionuclides possible and practicable to organize.

Collection should be made in containers suitable for the waste, having due regard to its physical, chemical, biological and radioactive properties. Due regard should also be taken of any specific approved packaging requirements of the final disposal route. Waste bags/containers should not be over-filled such that their integrity is compromised. When selecting packaging for biomedical radioactive wastes, it is necessary to consider the different types and properties of the waste generated, and also the future waste treatment method (Section 5) [1, 10].

Segregation of waste at the point of generation is an essential component of the waste management process. Storage for decay is particularly important for medical radioactive wastes, since many of the radionuclides used in medicine are short lived and the activity of the radioactive wastes produced is well defined. Practical experience shows that segregation can be used to deal with the large volumes of medical radioactive wastes that are produced, such that most of the wastes can subsequently be disposed of as inactive refuse. In most instances, it is convenient to segregate wastes according to their half-life, e.g.:

— wastes with a half-life of about 10 hours or less;
— wastes with a half-life of less than 10 days;
— wastes with a half-life of less than 100 days;
— waste with a half-life of greater than 100 days.

Further considerations for segregation should include such criteria as:

— Non-radioactive and radioactive materials;
— Radionuclide and activity content;
— Physical and chemical form;
— Spent sealed sources;
— Non-radiological hazards (toxic, biological, carcinogenic, infectious, flammable, etc.).

(a) Liquid wastes

Liquid biomedical waste should be collected and segregated in accordance with the particular procedures accepted at the establishment, considering not only current requirements, but likely developments in the future [11]. Liquid radioactive wastes that meets clearance levels (Section 8.1) can be discharged directly to an approved drainage/sewage system such as a municipal sewer. In some circumstances the biological hazard makes the

radioactive waste unsuitable for immediate release, hence the necessity for deactivation prior to discharge. The liquid waste may also contain carcinogenic chemical products which may also contain ethidium bromide which may need disposal as chemical waste. If meeting all release criteria, namely radiological, chemical and biological, can not be assured, biohazardous radioactive waste must not be discharged directly into a drainage/sewerage system.

Liquid waste should be collected, segregated and characterized, as far as possible at the point of origin according to its physical, chemical, biological and radiological properties.

It is necessary to segregate liquid wastes taking the following criteria into account:

— Radionuclide content and activity;
— Half-life of radionuclides and suitability for decay storage;
— Organic/aqueous liquids;
— Non-homogeneity of waste (sludges);
— Infectious hazard;
— Chemical hazards;
— Flammability.

Segregation is required in order to minimize waste hazards and to facilitate subsequent processing of waste. The segregation of waste at the point of origin is more efficient than performing segregation after mixing. For small volumes of immiscible liquids, segregation can be achieved by using simple laboratory equipment (e.g. separating funnel).

Chemically toxic or carcinogenic waste which is incompatible for release to the environment must be collected separately in order to avoid uncontrolled chemical reactions. These wastes should be sent for appropriate waste treatment as required by the regulatory authority.

Biologically contaminated radioactive liquid waste must be collected separately and should be treated to deactivate (e.g. autoclaving, chemical disinfection) all infectious contaminants [1].

(b) Solid wastes

Collection of solid biomedical radioactive wastes normally involves distribution of a range of suitable containers throughout the working area to receive discarded radioactive materials. These containers should be lined with primary packaging, such as a heavy duty plastic bag. The containers should be brightly colored (e.g. yellow) with the radiation symbol clearly displayed so as to distinguish them from bins for inactive wastes. It is advisable to have a range of types and sizes of containers for segregation of the different types of solid biomedical radioactive wastes at the time and place of production. Due to the biological hazard of these radioactive wastes, lidded containers are advised for their collection. Refuse cans/bins with foot operated lids are particularly recommended. They should be lined with heavy gauge plastic bags which can be sealed and removed. Waste collections must be scheduled so that biohazardous materials do not deteriorate in the refuse bins.

Special consideration should always be given to the management of contaminated sharp objects, such as needles and syringes, scalpel blades, blood lancets, glass ampoules, etc. These items commonly referred to as “sharps” are usually suitable for management as dry solid radioactive waste, although very small amounts of liquid might remain inside the needles/syringes.

Where treatment is by incineration, which is obligatory in some countries, heavy duty cardboard, waxed cardboard or polyethylene/polypropylene containers, clearly labeled as sharps containers, should be used to collect these wastes. Containers should be no more than three quarters filled before sealing. Where there is no incineration facility available, it may be more appropriate to collect sharps in metal cans of approximately 5 L or 10 L capacity. When filled, the cans can be firmly lidded and transfer to a centralized waste processing facility or to landfill disposal site (when the waste composition allows this option). Regulations for biohazardous waste in some countries, e.g. Belgium, require hermetically sealed polyethylene drums to be used instead of plastic bags not only for sharps but also for blood contaminated wastes.

Wherever possible, accumulation of damp wastes should be avoided where there is a requirement for long term storage. Significant moisture can lead to undesirable and possibly dangerous chemical and biological reactions whilst the waste is in storage. In such circumstances, damp or wet medical material should be drained, de-watered or dried to the extent possible, consistent with other safety concerns, before it is placed in waste receptacles. The addition of a moisture sorbent such as vermiculite may be advantageous. Refrigerating or freezing carcasses and similar remains is recommended.

4.3. PACKAGING AND LABELLING

Appropriate packaging, and correct usage of such packaging is an essential component of the waste management system for biomedical radioactive waste [12].

Choice of the proper types of materials and package style is necessary to minimize waste volume, provide reliable containment during storage, facilitate handling and simplify subsequent treatments. Packaging considerations for waste to be stored include:

— the nature of the waste to be stored;

— the expected time period for storage, with the possibility of extended storage;

— any further treatment necessary for the packaged wastes, i.e. deactivation, combustion, shredding, compaction prior to long term storage and/or final disposal;

— further handling and movement requirements that the packaging must withstand without sustaining damage or deterioration;

— compliance with any existing national and local safety standards;

— compliance with any packaging requirements of the organization that will undertake treatment or final disposal of the wastes;

— ease of closure/sealing of the radioactive waste packages to prevent dispersion/seepage of contents;

— ease of labeling of the package for purposes of future traceability of origin and identification of the waste contents;

— ability to contain foul odors and to obscure visually offensive wastes;

— ability of the packaging to withstand, without deterioration, the full range of temperature variations likely to be encountered, i.e. ability to withstand freezing without becoming brittle and liable to fracture;

— suitability of shape and size of the filled packages to optimize use of the available storage arrangements.

Plastic bags for containment of medical radioactive waste should meet certain manufacturing criteria:

— be of a maximum nominal capacity to meet the needs of the establishment;

— meet the performance specification standards of the establishment or an appropriate standards setting body;

— match the containers or fittings in use in the working areas;

— when destined for steam sterilization, be suitable for this treatment and carry an indicator strip to show that they have been subject to successful treatment;

— be of an appropriate color to be easily recognized for correct segregation of solid radioactive waste which may be biologically hazardous;

— take into account the final method of disposal.

In all instances:

— Plastic bags must be effectively sealed before handling;

— The maximum weight contained in any bag should be compatible with its holding capacity and any manual handling weight restrictions;

— Bags are to be handled by the neck only, and under no circumstances are they to be clasped against the body. Bags must never be thrown or deliberately dropped during handling operations;

— Check that the seal on any waste storage bag is intact at the end of any movement;

— Check that the appropriate gauge of plastic bag has been used dependent on the waste being collected. Where appropriate, double-bagging should be used;

— Bags must never be more than two-thirds filled to permit future safe handling by the neck of a securely sealed bag.

The following requirements should be met when selecting packaging suitable for containment of sharps:

— Packaging should be puncture resistant and leak proof, even if toppled over or dropped;

— It must be capable of being handled and moved within the working area whilst in use with minimum danger of the contents spilling or falling out;

— The container should have an aperture which, in normal use, will inhibit removal of the contents, but will ensure that it is possible to place items into the sharps container using one hand, without contaminating the outside of the container;

— Have a firm closure device attached for sealing when the container is no more than three quarters full;

— Be marked with the words "Danger, Contaminated Sharps Only". Destroy by incineration or “to be incinerated”;

— Be of dimensions compatible with the clearance measurement system;

— Be provided with a handle(s), that is not part of the closure device. The position of the handle must not interfere with the normal use of the container;

— Be made of materials which can be incinerated;

— Have a horizontal line to indicate when the container is 3/4 full, and marked with the words “warning — do not fill above the line”.

The use of plastic bags or single use polyethylene drum containers for medical radioactive waste containment have the advantage that damp wastes will not seep through them and contaminate the floor. A double wrapping with plastic bags is advisable. Very heavy, wet wastes should not be packaged in plastic bags due to the possibility of rupture of the seam of the plastic bag with resultant loss/seepage of contents. When available, single use disposable plastic containers with lids (volume range 10 L–200 L) should be used. These containers once lidded and sealed are especially useful as they are leak free, even if the container becomes accidentally inverted during further handling. Additionally, the containers have the advantage that they are suitable for incineration in furnaces designed for plastics. The fixed geometry of hermetically closed polyethylene containers makes them ideal for easy handling and a useful geometry for calibration and automation of activity measurement. Their shape also makes them suitable for optimized close stacking for short-term storage prior to disposal. Although these containers are unsuitable for sharp objects as they are not puncture resistant, they are of value where large quantities of radioactive waste which is biologically hazardous, offensive in nature or with a potential for fluid leakage requires containment, e.g. blood filled organs or tissues, vials/tubes of scintillation wastes. It is essential that the lid is firmly pressed down when sealing these containers to ensure there will be no fluid seepage. These containers are also advantageous in that they may retain offensive odors during short-term storage prior to treatment and/or disposal of the waste.

Liquid waste should be collected in suitable containers or tanks selected according to the chemical and radiological characteristics and volume of the waste, and the handling and storage requirements. In general polyethylene containers should be used in preference to glass, as they are more robust and can be easily and safely volume-reduced when required. For special waste, including organic solvent, the container should permit swelling (i.e. not rigid, but flexible) and the cap should not be airtight. In this case, high-density polyethylene (HD-PE) is preferable to low density polyethylene (LD-PE). With tritiated wastes, a glass container is preferred. If polymer containers are needed, polycarbonate can be used. In all cases, care should be taken to avoid pressurization of the containers due to the expansion of liquids and the evolution of gases and vapors. It is usual that all storage containers are stored in secondary containment able to collect the contents of the primary storage vessel. Color coding of containers can be used for segregated waste streams, and the color reference should be well

documented. Depending on the scale of the waste management operation, bar codes or functional data numbering may be indicated. Fermentation should be avoided by the addition of neutralizing agents during storage for decay.

A sufficient number of containers must be provided so that the mixing of wastes having significantly different hazard potentials (biological or radiological) can be avoided. Before storing biohazardous radioactive wastes in metal containers, the corrosive nature of the liquid to be contained must be considered, along with the duration of the storage time. If the waste requires steam heat sterilization prior to disposal, the container to hold the liquid should be suitable for this purpose, i.e. a heavy duty polypropylene container resistant to destruction by temperatures up to 130^{o}C. Glass storage containers should be avoided due to their fragile nature. A quality assurance programme should include audits of reusable liquid storage containers to ensure they remain suitable for continued use (Section 9.3.2).

In more sophisticated establishments where large volumes of biomedical radioactive liquid wastes of similar origin are produced, use of holding tanks may be the preferred method for containing liquid wastes prior to discharge or off-site transport prior to treatment. It is advisable to have a minimum of two holding tanks. One tank can be filling, while the other tank is subjected to any necessary chemical deactivation and decay storage prior to discharge. In very large establishments, additional holding tanks may be necessary to facilitate segregation of liquid radioactive wastes into short lived, long lived and biomedical hazardous.

5. STORAGE AND TRANSPORTATION OF BIOMEDICAL RADIOACTIVE WASTE

5.1. GENERAL CONSIDERATIONS FOR STORAGE OF WASTE

On-site interim storage of biomedical radioactive waste may be necessary for different reasons:

— storage for decay;
— storage before pretreatment/treatment;
— storage prior to returning to vendor.

Although the safety requirements in the case of temporary storage may be less stringent than for long term storage, nevertheless adequate attention should be paid to the needs of shielding and prevention of leakage as well as to the specific requirements of chemical and biological components of waste (freezing, refrigeration, neutralization, sterilization, etc.).

Each facility should define a policy for storage of biomedical radioactive wastes. The design of the storage facility for unconditioned radioactive waste should reflect governmental guidance and regulation, and include the following features [13, 14]:

— The storage area should be used solely for the purpose of holding biomedical radioactive wastes, which may or may not be biohazardous. It is not permitted to store any other materials in this area;
— The storage area should be constructed of rigid building materials;

— The area should be well illuminated, either by natural or artificial light. Installation of electric lighting should provide for protection from spark ignition when volatile organic wastes are unavoidably stored;
— The storage area should be physically isolated, well away from areas where potentially flammable or explosive materials are located, or where employees or other persons might receive unnecessary exposure;
— The storage area should be sited away from routes available for public access, but it should be readily accessible for transportation of wastes, especially from vehicular traffic if required;
— The storage area should be appropriately ventilated;
— It should be appropriately labeled outside with a radiation symbol and warning of any other chemical or biological hazard. It is recommended that the name of the person responsible for supervision of the radioactive waste storage area, along with contact daytime and out of hours telephone numbers, should also be displayed;
— The storage area should be of sufficient size to hold, in a well organized way, all of the radioactive wastes requiring storage, with adequate capacity to deal with contingency arrangements;
— The storage area should have a system for segregation of the various categories of radioactive packages, i.e. racks, drums or bins for storage of plastic bags of waste. There should be no mixing of wastes destined for different routes of management;
— Storage of food wastes in the vicinity of the radioactive waste store is to be discouraged, as this encourages infestation by insects or rodents;
— The storage area should have an impervious, well drained flooring, preferably with wash down facilities;
— Washing facilities for employees working at the facility should be provided adjacent to or in close proximity to it;
— An area for protective equipment and materials for dealing with spills should be provided at or in the facility;
— Appropriate monitoring devices (radiological, chemical and physical) should be provided as needed;
— Appropriate inventory/log book of stored waste should be maintained;
— Provision for floor protection should be made in the event of accidental floor contamination.

The size and capacity of the storage area should reasonably reflect its expected inventory. A simple storage room that provides the above features and is located at the waste producing institution may be adequate for small amounts of waste. Figure 2 illustrates a small storage facility typically found at a hospital.

The general requirements for a radioactive waste storage area should be complied with, when either selecting suitable existing facilities for short term radioactive waste storage, or when designing a purpose-built facility. A careful assessment of both current and possible future short term decay storage requirements should be considered. The usual radiological protection requirements should apply regarding handling and storage of potentially active wastes in even the simplest of facilities. Local regulatory controls may require additional

design features due to the potential biohazardous/infectious nature of the wastes to be stored, i.e. walls sealed with an impervious paint finish to facilitate easy cleaning for infection control purposes.

5.1.1. Security

A radioactive waste storage facility should be well protected against unauthorized human intrusion. It should be constructed, operated and maintained in such a way that unauthorized removal of radioactive wastes is prevented. An adequate locking mechanism should be provided to prevent unauthorized access. It is recommended that physical barriers, including fencing and an intruder alarm system be installed. Should intrusion occur, security arrangements should ensure that any unauthorized removal of waste would be promptly discovered and effective measures initiated to recover the missing material.

FIG. 2. Small store typically found on the premises of a hospital.

5.1.2. Protection from fire

When assessing the overall safety of a radioactive waste storage facility, it is necessary to consider the possible consequences of an accidental fire and take steps to minimize its risk. The careful selection of non-flammable construction materials when building the radioactive waste storage facility will greatly reduce this hazard. The radioactive waste storage facility should not be used to hold any highly flammable or highly reactive materials. Gas or oil fired burners must not be used for heating, and any previously existing supply lines for these fuels should be capped at a location well away from the waste storage facility. Heating should not be able to come into contact with packages.

Liaison with the local fire fighting authority is necessary. Their advice should be sought regarding provision of fire fighting equipment in the vicinity of the radioactive waste store. Potentially flammable wastes requiring storage, i.e. organic scintillation fluids in vials, should be adequately sealed in heavy-gauge plastic bags, and stored in metal drums with lids. These flammable wastes should be stored in a specific area of the facility that is physically separated from the other wastes and equipped with a high quality fire detection and suppression system.

5.1.3. Protection from insects/rodents

Insects and rodents can present a serious threat to containment of packaged radioactive wastes, especially in short term storage facilities where plastic bags may be prevalent. Protection from insect and rodent infestation is particularly relevant where biohazardous radioactive wastes are stored. Their consumption and dispersion via insect/rodent excretions can result in the spread of both radioactive contamination and potentially infectious materials. The insect/rodent control programme for a waste storage facility should be carried out in co-operation with the local health department or other agency authorized to deal with these problems, and meet all applicable hygiene requirements.

Insect/rodent infestation problems should be correctly identified, including the magnitude of the problem. Measures should be taken to reduce the routes of entry of insects and rodents into the radioactive waste store. Any defects in construction materials should be repaired. The door to the radioactive waste store should be closely fitting, with gaps at the bottom sealed by a firm bristle or metallic sealing strip. Should areas of food or food waste storage be located in the vicinity of the radioactive waste storage facility, these should be relocated as they are a possible encouragement to infestation by insects and rodents. Commercially available poisons, often in prepared trays, are available. These should be placed both within and outside the radioactive waste storage facility. Any dead insects or rodents recovered should be monitored and assessed for the presence of radioactivity.

A range of insect and rodent traps are commercially available. Their use should be considered where insect/rodent populations may have developed resistance to chemical methods of pest control. Trapping may be preferable to poisoning if there is evidence that these intruders are spreading contamination.

5.1.4. Protection from temperature extremes

Waste storage should take into account potential extremes of temperature which should be avoided. Extreme heat can cause biomedical waste to putrefy greatly increasing infectious hazards, possible bursting of container and obnoxious odors. Extreme cold is not as critical as extreme heat, however, liquid aqueous waste should be protected from frost to avoid the breaking of aqueous liquid containers. Temperature control is necessary in a waste storage facility where temperature extremes are known to occur.

5.2. ON-SITE STORAGE OF BIOMEDICAL RADIOACTIVE WASTE

5.2.1. Storage for decay

Storage for decay is particularly important for radioactive wastes from medical uses of radioisotopes since many of the radioisotopes used are short lived and the activity of the radioactive wastes produced is well defined. In recent years the policy for management of biomedical waste in many countries has been changed considerably in respect to storage of short lived waste. Decay storage, traditionally practiced by small and medium size establishments, has now spread to larger establishments, such as big university establishments. This evolution is due to a significant increase of the processing and disposal cost invoiced to the establishments and problems associated with transportation of waste to

the centralized facilities. Practical experience shows that decay storage is suitable for wastes contaminated by radionuclides with a half-life of less than or equal to about l00 days. Particularly where large volumes of biomedical radioactive wastes are produced, it may be more convenient to partition the short term decay storage facility to provide areas for storage of wastes according to their half-life, as previously described. Figure 3 illustrates typical decay storage of frozen animal carcasses. For containerized waste, Fig. 4 shows an arrangement for adding or removing items in decay storage, and Fig. 5 shows a simple stacking arrangement for lesser amounts of waste.

Wastes with a half-life of greater than 100 days can be accumulated in the decay storage area until sufficient volume and/or activity is collected for transportation to a centralized waste processing facility for treatment, conditioning and disposal.

A decay storage period of ten half-lives will reduce the initial radioactivity to less than one thousandth of its original radioactivity, which in many cases means below the clearance levels for release, depending on the local regulatory requirements, (the concept of clearance levels of radioactivity is presented in Section 8.1). Decay storage to clearance level is almost always the preferred waste management option, both scientifically and economically. Certain categories of biohazardous radioactive waste which have been subjected to pretreatment, so that they are no longer a biological hazard, can be disposed of at clearance levels. All relevant regulations for disposal of waste below the clearance levels with municipal refuse must be followed. In places where a well organized municipal refuse collection system does not exist, the operator may need to seek the advice of the waste licensing authority. Decay storage and subsequent disposal as municipal refuse requires accurate administrative control measures and very careful waste segregation and activity measurement, both at the origin of waste production and at the end of the decay storage period. Waste contaminated with hazardous chemicals must be excluded from disposal as municipal refuse and should be routed to a suitable processing/disposal facility.

5.2.2. Storage of waste before treatment

It is usual practice for all health care institutions to have a facility for on-site interim storage of radioactive waste. In nearly all hospitals, the waste from nuclear medicine diagnostic procedures is dealt with “in house” rather than at a centralized facility. Interim storage is usually in a room with segregated storage areas for the waste of different half-lives. A separate area with metal cabinets for storage of flammable organic liquids and a freezer/refrigerator cabinet for highly putrescible wastes (animal carcasses or human organs and tissues) may also be installed. Where waste is managed on-site at a medical facility with incineration capabilities, most waste will be promptly routed for incineration.

In circumstances where generated solid waste has a half-life of greater than 100 days this waste could be collected and stored before transportation to a centralized waste processing facility for further treatment, storage and/or disposal. The original packaging in which such wastes are accumulated and the segregation methods used must reflect the acceptance requirements of the centralized facility and any subsequent treatment the waste will be subjected to. Choice of the proper types of materials and package style is necessary to minimize waste volume, provide reliable containment during interim storage, facilitate handling and simplify subsequent treatments.

FIG. 3. Animal carcasses frozen in plastic bags.

FIG. 4. View of the decay storage facility during loading of radioactive waste.

FIG. 5. Drums stacked for storage.

5.2.3. Storage before returning to vendor

In some countries(e.g. USA), it is common for some medical radionuclides that are used for therapeutic purposes (e.g. ^{89}Sr or ^{192}Ir strands) to be supplied in pre-dispensed patient doses, complete with gloves, cotton wool, swabs, etc. The radionuclide is administered to the patient and all of the waste material is re-packaged into the original box provided by the manufacturer, and is returned to the supplier.

It is normal practice in many countries for technetium generators to be supplied in re-usable Type A packages. The generator is usually decayed for about six weeks before being repackaged and labeled, using labels provided by the vendor, and returned via the transport system at the time of delivery of a new generator.

Interim storage capacity should be available for spent sealed radiation sources prior to their return to the original supplier. It is essential to liaise with the supplier to ascertain the conditions for return of spent sealed sources. Measurement of the remaining level of radionuclide activity and an appropriate integrity test to prove that the source is not leaking will be required.

5.3. RADIOACTIVITY SURVEY

An essential part of any radioactive waste programme is the measurement of the radioactivity associated with a waste package (i.e. plastic bag, drum or other container). The measurement, often called a survey, is an integral part of the waste pretreatment, i.e. when it is first collected, and should be repeated whenever the waste packages are handled or moved (placed into storage, retrieved, or transported off-site). This serves to protect workers handling the package, helps prevent accidental spread of contamination, and provides an independent check of the record keeping system.

In surveying a waste package, independent measurements are usually made to determine:

(1) dose rate, mSv/h, or activity in Bq, both of which are measured at a specified distance from the container;

(2) the radioactivity concentration of the waste and/or isotopic content (Bq/g or Bq/L);

(3) any radioactive contamination of the outside surfaces of the package. These procedures are described in the following paragraphs.

Measuring the radioactivity from within the waste itself is important for handling the package and verifying records. The initial activity measurement provides information on the level of radioactivity present in order to determine further treatment requirements. A second measurement is required where waste is to be released at clearance levels. Gamma radiation with energies above 100 keV is easily detected allowing rapid and reliable measurements, for example of plastic bags, to be made on a semi-automated basis. This equipment is well suited for monitoring of low level, solid wastes from laboratories and medical use of radionuclides (Fig. 6). Waste containing low energy gamma emitters or the high energy beta emitters such as ^{32}P can be quantified using commercially available instruments and appropriate conversion factors to correct the measured activity for losses due to absorption and geometry (Fig. 7). Portable commercial instruments with sensitive detectors adapted to the radiation characteristics of the waste are useful but do not always allow the estimation of residual activity in numerous waste configurations.

Low energy beta emitters are very difficult to measure to any degree of accuracy. Quantities of such nuclides are best estimated from knowledge of how the waste was produced, and extrapolating from the quantity of radioactive materials used and data on typical waste arisings. More recently, instruments have been developed using Ge, NaI(Tl)- and plastic detectors in a lead shielding. This instrument can measure even low energy gamma contamination in low energy β-waste, except tritium. Minimum detectable levels of activity are in the range 2–6 Bq/kg for ^{14}C and ^{35}S, which is adequate when wishing to use clearance levels as a means of final waste disposal.

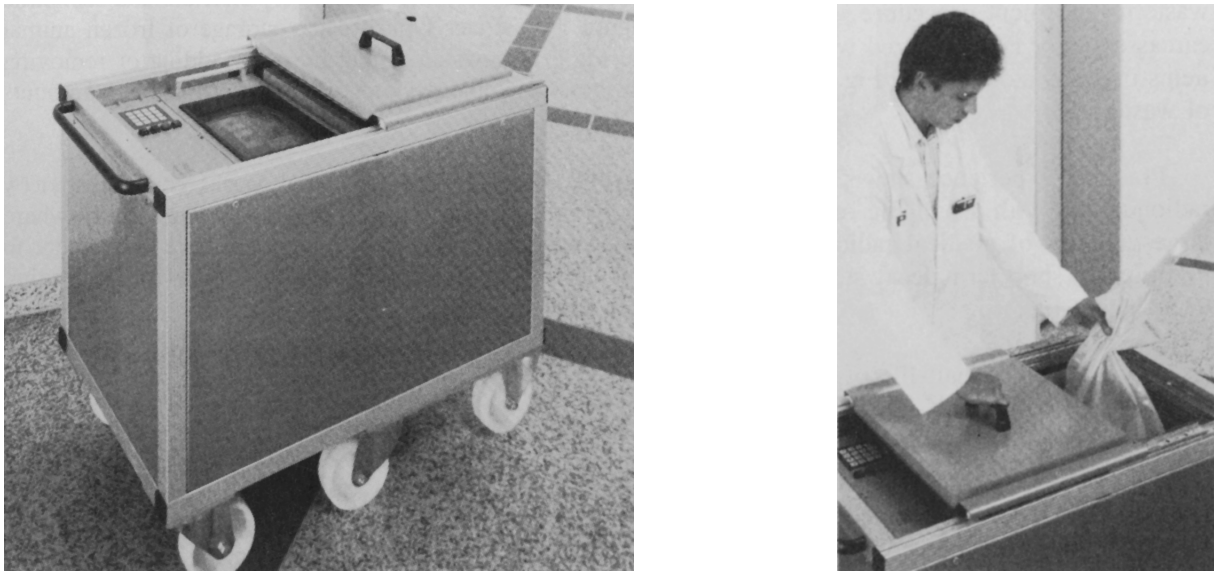


FIG. 6. Monitoring bagged waste.

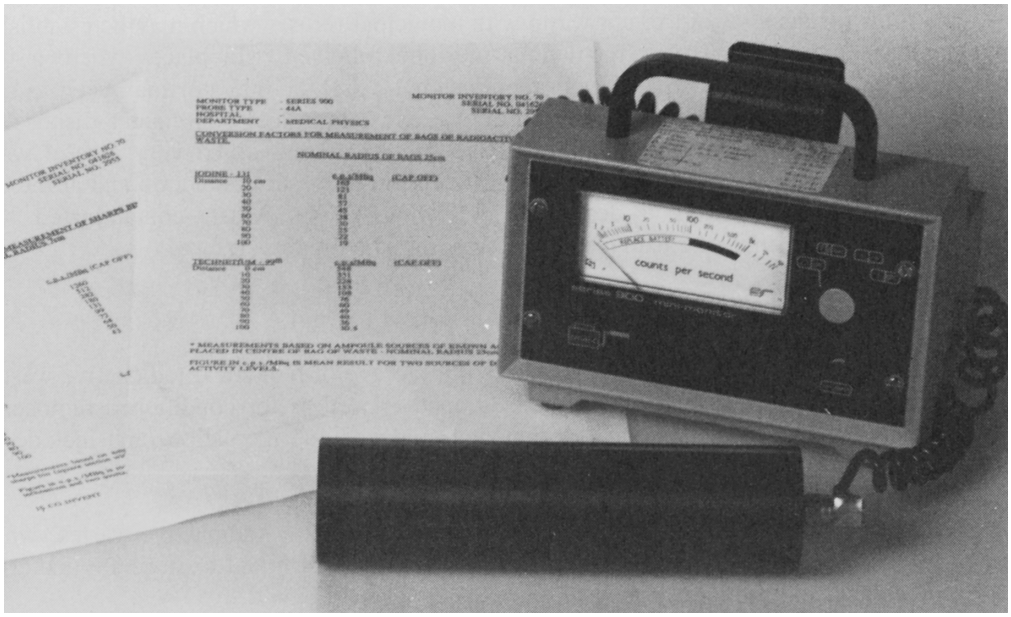


FIG. 7. Survey meter with conversion charts.

A survey for transferable surface contamination is especially important before the package is handled or moved. This is best accomplished by physically wiping the container with a semi-porous material such as filter paper or a cotton swab. If possible, it is best to wipe over the entire surface. The wipe material is then checked for radioactivity with a survey meter. Very sensitive measurements can be made if the wipe is counted by liquid scintillation. For such a measurement, the wipe is simply folded and dropped into a standard vial containing the scintillation liquid which is then placed in the counter. A good quality scintillation counter can count several dozen vials automatically and provide the results in printed form.

The unexpected presence of radioactive contamination on a waste package often indicates that the package itself has been breached or physically damaged. For biological radioactive waste this could also indicate the possible presence of pathogens on the surface. In all cases the area around the suspect packages should be isolated, and appropriate warning notices displayed whilst plans are developed to identify the source of contamination and to contain it. This is often done by placing the damaged package into a secondary bag or "overpack" container.

5.4. TRANSPORTATION

5.4.1. Considerations for transportation

Transportation of biomedical radioactive waste is normally required when removing waste:

— to a central facility for further treatment (conditioning) and disposal;
— to a disposal facility or landfill disposal site;
— to return to vendor.

Prior to transportation, specific requirements for biomedical radioactive waste should be taken into account. Transportation of liquid biomedical radioactive waste must be in appropriately designed containers. Unconditioned putrescible radioactive wastes for transfer to a centralized facility must remain frozen, both prior to and during transportation, especially in hot climates. These wastes should be transported or transferred in special refrigerated vehicles. Frozen animal carcasses can be transferred to a central receiving location ready to be loaded onto a vehicle that is either refrigerated or equipped with cabinets containing solid carbon dioxide (dry ice). The refrigeration temperature during transport should be controlled, and the vehicle should be fitted with a warning device in the event of failure of the freezer.

There should be documented contingency arrangements to be followed in the event of failure of the freezer whilst transporting biohazardous radioactive wastes. Documentation accompanying biomedical radioactive waste to be transferred should contain sufficient information for its recipient to handle the wastes safely and in accordance with requirements of any applicable regulations. As a minimum, the activity, isotope composition, chemical composition, biomedical content, volume, weight, dangerous properties of transported material, date of transport and responsible person should be recorded. The regulatory authority may require copies of all transfer documents, or require that they be available from the shipper and/or receiver for inspection.

Written procedures should be in place detailing arrangements for transport of waste to the centralized facility and staff should be appropriately trained in their implementation. The documents should also include details of contingency arrangements to be followed in the event of an accident/incident during transport.

Documentation accompanying biomedical radioactive waste, should be readily available for inspection during transport. The documentation should be handed over by the driver to an appropriate person at the centralized facility for checking, prior to the radioactive consignment being unloaded.

5.4.2. Compliance with transport regulations

Transport of biomedical radioactive waste should be conducted in a way that ensures the safety, not only of those involved in the transport operation, but also for those who could be affected as a result of transport operations or of an accident during transport. This means that detailed regulations and guidances are required for preparing waste to be transported as well as for the carriers.

Biomedical radioactive wastes should be adequately packaged and contained for transport by road, rail or sea, according to current national regulatory requirements. These national requirements are usually based on international recommendations or agreements, which are in any case valid for international transportation of the wastes. The packaging requirements for transport of radioactive materials are detailed in IAEA Safety Standards Series No. ST-1 [15] This document includes details of general safety principles, activity limits, testing requirements for package types, storage in transit and test and inspection procedures. Drivers transporting radioactive materials have to be suitably trained and carry contingency plans on the vehicle detailing action to be taken in the event of an accident.

Off-site transport and on-site transfer of radioactive waste should be carried out in compliance with any other regulations which specify requirements for handling, shielding, labeling of the waste, dealing with a spill or other accident scenarios.

5.4.3. Security and containment in transit

Radioactive packages should be checked prior to loading onto a vehicle to ensure that the packaging remains intact and able to withstand conditions of transportation. Where any doubt exists, the package should be securely overpacked to ensure it retains its contents.

When loading packages onto a vehicle, packages with higher surface radiation dose rates should be loaded last, such that they are furthest away from the driver. An inventory of the radioactive consignment should be prepared, which identifies uniquely all of the packages being transported, so that any theft or loss of packages would be readily realized.

It is important to secure the load in the vehicle in order to prevent the packages from shifting during transport, as this may damage them. Various methods of securing the load can be utilized, to include the use of cages, tie down facilities or containment nets.

Once biohazardous radioactive waste is loaded onto a vehicle, the vehicle should remain under close supervision to prevent unlawful tampering with the contents. It is not advisable to leave a vehicle unattended and out of sight of the driver whilst radioactive wastes are being carried, even though the vehicle is securely locked.

6. TREATMENT OF BIOMEDICAL RADIOACTIVE WASTE

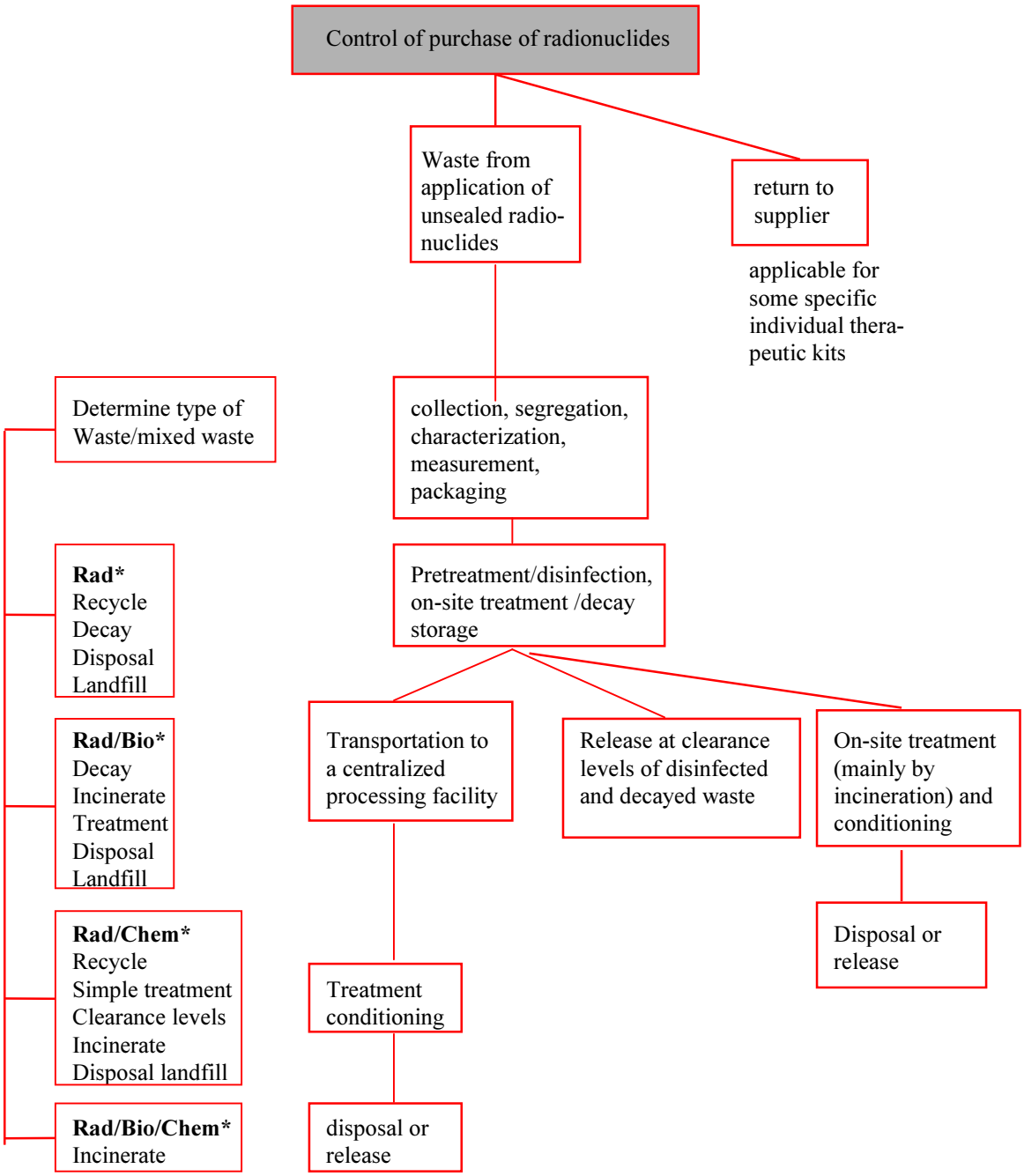
6.1. INTRODUCTION

Collection, handling, segregation and packaging of biohazardous radioactive waste utilize essentially the same practices that are normally associated with good radioactive waste management. However, the practices used for radioactive waste management are not usually sufficient to control any biohazardous waste component. The Universal Precautions used in healthcare facilities (see Section 2.4.3.) should be considered together with contamination control and radiation protection procedures used in the nuclear industry.

Biohazardous radioactive waste cannot always be treated using the same methods as non-radioactive biomedical waste. Autoclaving is not a suitable method to destroy a microbiological hazard when the waste is contaminated with radionuclides such as ^{125}I or ^{3}H. Compaction also could not always be recommended for processing of biomedical radioactive waste because of possible generation of infectious aerosols. Brief descriptions of the basic treatment methods for biohazardous waste are presented below, along with their appropriateness for management of biomedical radioactive wastes.

6.2. SELECTION OF MANAGEMENT STRATEGIES FOR BIOMEDICAL RADIOACTIVE WASTE

Based on the waste types described in Section 2 and other general considerations, a biomedical radioactive waste management strategy can be developed that best fits local needs and circumstances. The local needs and circumstances also include the important aspect of demonstrating regulatory compliance. A general flow chart for managing medical radioactive waste is shown in Fig. 8.



Key to abbreviations:

Rad: Radioactive Waste.
Bi: Biohazardous waste.
Chem: Hazardous chemical waste.

*Activity measurement throughout the waste management process is assumed.

FIG. 8. Example of a flow chart for managing medical radioactive waste.

There are essentially two strategies for medical radioactive waste management that may exist, dependent upon the facilities and the extent of use of radionuclides within a country:

(a) on-site waste management strategy;
(b) a combination of on-site and a centralized waste management strategy.

The latter may be appropriate, especially if a country produces a significant amount of waste that contains long lived radionuclides. A centralized strategy would be recommended for most long-lived nuclides and also as a cost effective way of treating long-lived biomedical radioactive waste which is contaminated with hazardous chemicals. An on-site strategy would be advantageous for the vast majority of short-lived radionuclides used in medicine. In such cases, the necessary expertise for waste treatment can be developed within the institutions using the radionuclides, possibly by the project managers or clinicians themselves, or their designated subordinates. In either strategy, control by the regulatory authority is required and must be maintained.

In developing a waste management strategy for biomedical radioactive waste, practices and concepts may vary considerably from one country to another. The actual on-site strategy for handling biomedical radioactive waste may be determined by the non-radioactive biohazardous waste disposal needs. The following basic principles should be carefully considered when developing the waste management strategy:

— Only proven technologies should be considered, and these must be relevant to the types and characteristics of the biomedical radioactive wastes concerned;

— The technologies and the entire waste management system should be applicable to the conditions prevailing in the country. This includes the legal and regulatory structure as well as economic, social and physical conditions. Possible omissions and deficiencies should also be identified and their relevance carefully considered, i.e. status of the regulatory framework, control authority, environmental surveillance, baseline data, etc.;

— An integrated approach with application of the ALARA principle must be followed. This requires considering the entire sequence of waste management operations from waste generation and waste collection to final disposal, and all the related issues: every aspect of waste production, packaging, conditioning, storage and preparation for transportation, including regulatory, socio-political and economic issues. The interactions among all these factors should be analyzed and understood before the waste management strategy is developed, so that all wastes can be safely managed.

6.3. BASIC WASTE PROCESSING TECHNOLOGIES

There are several processes used in the treatment of biomedical waste including biomedical radioactive waste. Most of these processes can be categorized by the type of treatment techniques (mechanical, thermal, or chemical). These processes are described below.

Usually a limited amount of treatment of waste will be practiced at healthcare facilities. More complex treatment and conditioning is undertaken (where necessary) at a centralized waste processing facility. In many countries, hospitals manage their radioactive wastes on site, tending only to use a centralized facility for management of spent sealed sources.

6.3.1. Mechanical processes

Mechanical processes are used to change the offensive appearance of biomedical waste in order to facilitate waste handling operations or to process the waste in conjunction with other types of treatment. The two primary mechanical processes are compaction and shredding. Compaction involves compressing the waste into containers or boxes in order to reduce the volume. Shredding (including granulation, grinding, and pulping) breaks the waste down into smaller pieces. This process provides disfigurement of the waste and also prepares the waste for other types of treatment.

Compaction and shredding alone are not considered viable or major radioactive biomedical waste treatment methods. The primary reason for this restriction is that any microorganisms contained within the waste may be spilled or released during these processes and contamination may be widely dispersed [16]. Mechanical processes are often combined with chemical treatment to disinfect or sterilize the waste.

In cases where incineration is not available or the volumes of human and animal wastes are so low that it is desirable to treat them as they are produced, it may be feasible to use maceration/pulverization to render these materials liquid, so that they can be discharged via a liquid radioactive waste route. This also includes any necessary chemical deactivation to treat the biological hazard. This method of treatment is typically used for small laboratory animals.

The apparatus for this purpose uses basically the same technique as a liquidizer used to render food products into a liquid form. It consists of a lidded containment vessel with a series of high speed rotating blades in the base (Fig. 9). Use of a commercially available liquidizer designed for the catering industry has the added advantage in that its stainless steel construction can withstand the addition of chemicals, such as sodium hypochlorite, along with the water, to achieve both liquidization and chemical disinfection of the waste.

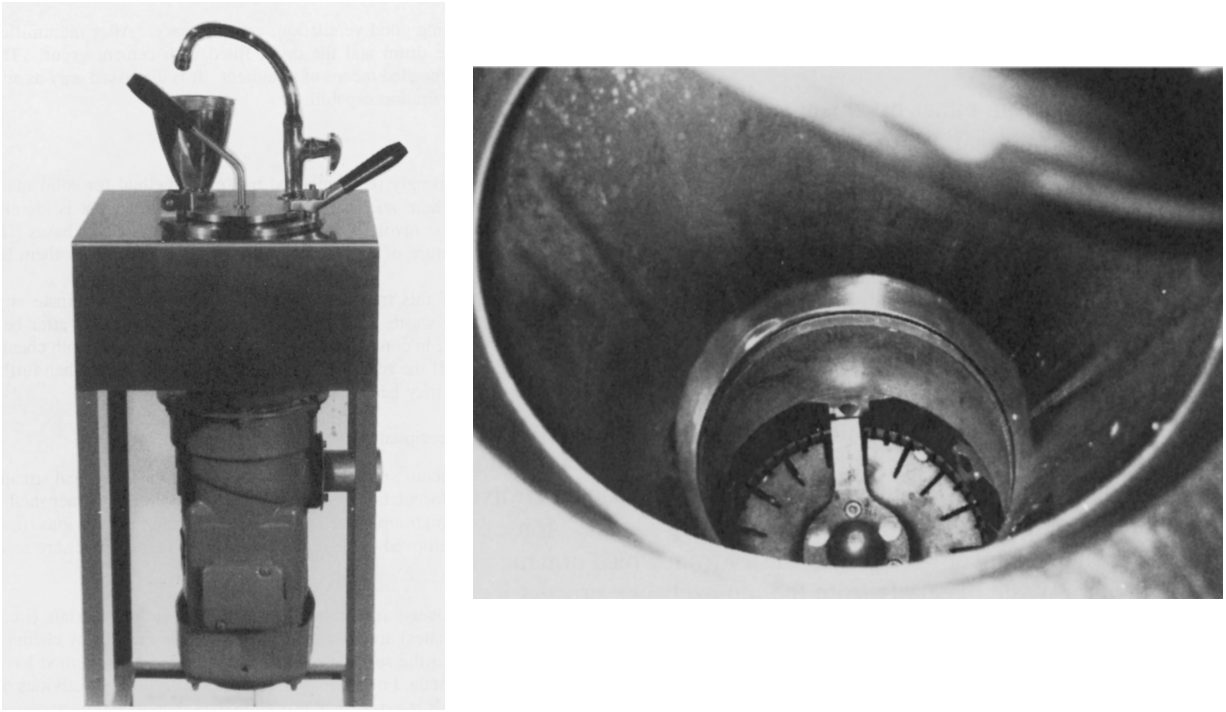


FIG. 9. Macerator.

6.3.2. Thermal treatment

Thermal processes biologically decontaminate biomedical waste by using heat as the primary means to destroy organics and microorganisms. Radioactive material is not destroyed by the thermal process but remains as a secondary waste or is released or diluted to the environment provided clearance levels are met. Many of these processes operate at temperatures over 100^{o}C, a temperature above which most microorganisms are destroyed. Thermal processes vary in the way in which heat is generated and applied to the waste. The most common types of thermal processes include steam autoclaving, microwave disinfection, dry heat and incineration.

A further type of thermal treatment is refrigeration/freezing. Some medical radioactive wastes require storage in freezer cabinets or chilled rooms in order to prevent putrefaction. Chilled rooms are only likely to be required where prolonged periods of storage are necessary or the volume of waste produced is large. For smaller volumes and shorter storage times, freezer cabinets are adequate, as they are more economical to purchase, operate and maintain. Freezer cabinets can be cooled either electrically or by use of solid carbon dioxide. Ideally the freezer temperature should be maintained below –20^{o}C. An alarm should be installed to warn of the mechanical or electrical failure of frozen storage facilities. Freezing/refrigeration is often a pre-treatment prior to the waste being incinerated.

Freezing of biohazardous radioactive waste for storage is not always necessary. In many instances, waste can be stored at higher than room temperature using appropriate packaging and preservatives. Some of these wastes may require deactivation before storage.

Incineration

Incineration is the most important treatment method for biomedical radioactive waste. Incineration uses controlled, high-temperature combustion to destroy organics in the waste materials. It is the preferred method of treating biomedical wastes including medical radioactive wastes because it produces a totally sterile residue with stack emissions being kept to acceptable environmental standards. Modern incineration systems are well-engineered, high-technology processes designed to completely and efficiently burn the waste whilst producing minimum emissions.

Ensuring complete combustion of the waste and monitoring stack emissions to ensure that they remain within acceptable limits are the main technical difficulties for medical waste incineration. The off-gas treatment system must control the release of chemically toxic or noxious effluents (HCl, SO_2, NO_x). Improperly controlled incineration can produce toxic compounds such as polychlorinated dibenzo-p-dioxins (PCDD) and dibenzofurans (PCDF).

Biomedical incinerators are appropriate for both on-site and off-side centralized facilities. Usually the on-site systems are much smaller with less capacity and provided with fewer options. There are several different types and sizes of medical incinerators (dual chamber, rotary kiln, etc.). A typical design for a well-engineered high technology system includes a multi-chambered controlled air system that is designed with several available options (Fig. 10). The types of options include a waste loading mechanism (hand loading, cart dumping, conveyor belt), an ash removal system(manual removal, automatic ash removal conveyor), heat recovery (boiler) and air pollution control. The off-gas cleaning systems usually include wet (NaOH- venturo) or dry (bag-house) scrubbers, rotary atomizer, carbon bed, HEPA filter, etc. Schematic diagrams of wet and dry scrubber systems one provided in

Fig. 11. A typical biomedical waste incineration system under construction is shown in Fig. 12.

The high temperature stack comes directly off the incinerator chamber. It is refractory lined and is only used as a by-pass when there is a problem with the pollution control devices. The low temperature stack follows the pollution control devices. Depending on the size of the system there is usually only a single pollution control device. In some larger systems and those operating at centralized facilities, several devices may be used in combination to meet local environmental requirements. The heat recovery boiler cools emissions. The boiler in turn produces steam to heat buildings and supply hot water. Energy sources for the incinerator can include natural gas; fuel oil or captured land fill gas. Resulting ash is usually sprayed with water as part of the removal method to avoid ash becoming dispersed.

A properly designed, operated, and well-maintained incineration system is environmentally acceptable and is the most cost-effective waste treatment method, particularly for biohazardous medical waste. Incineration not only sterilizes medical waste but also provides volume and weight reductions of greater than 90 percent. This process converts obnoxious waste, such as biomedical waste, to innocuous ash and renders sharps unrecognizable. Some incineration systems provide for energy recovery, and can be used for simultaneously disposing of hazardous chemicals as well as volume reduction of low level radioactive biomedical waste. Biomedical radioactive waste is readily disposed of using incinerator technology and is the thermal process of choice, particularly following decay to clearance levels.

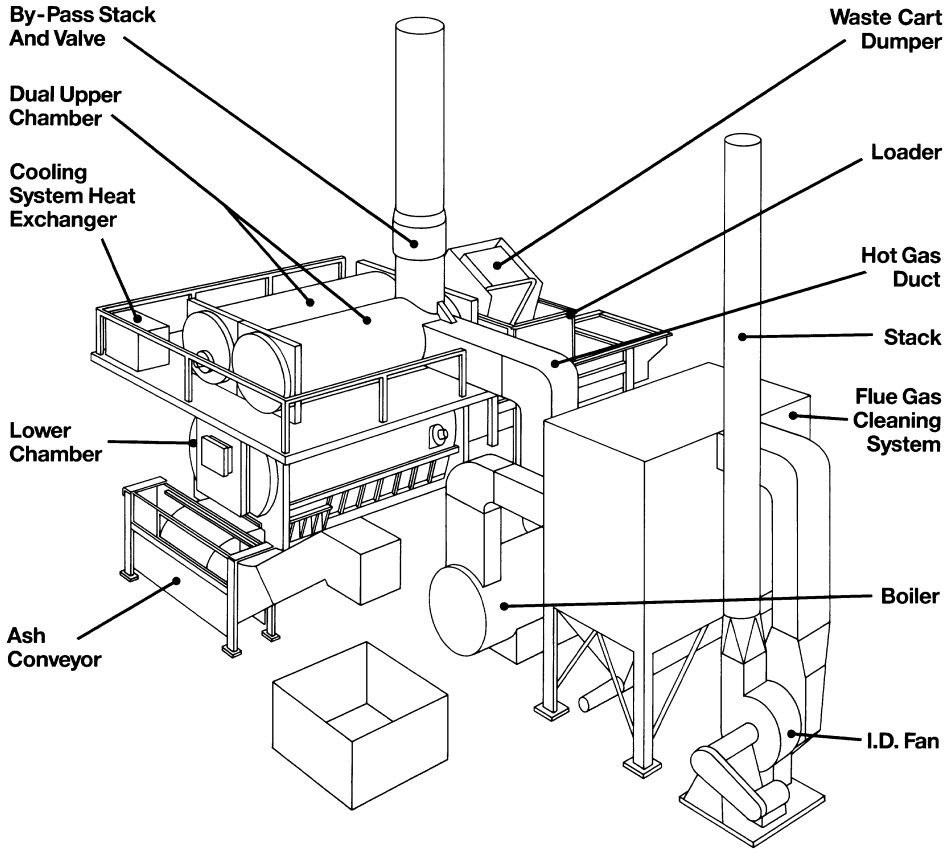
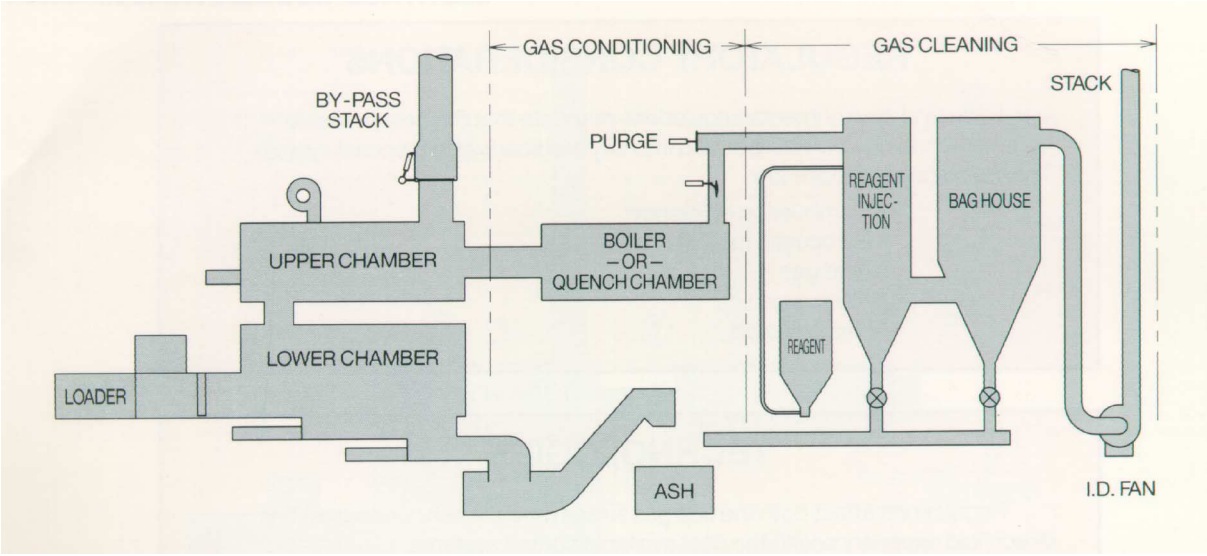


Fig. 10 Biomedical/radioactive waste incinerator.

Dry scrubber system for particulates and acid gases



Wet scrubber system for particulates and acid gases

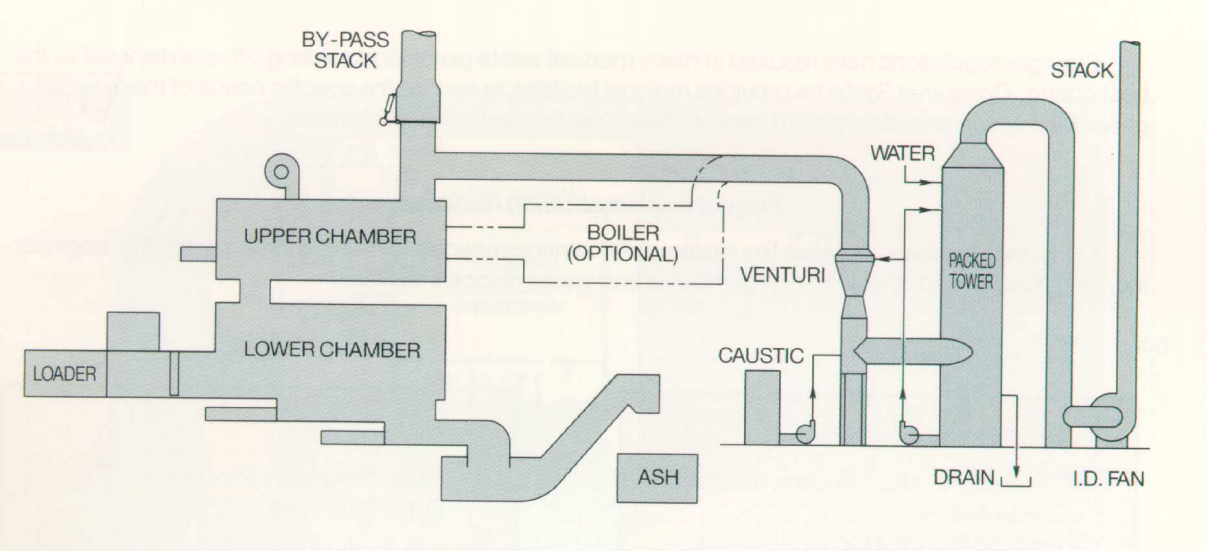
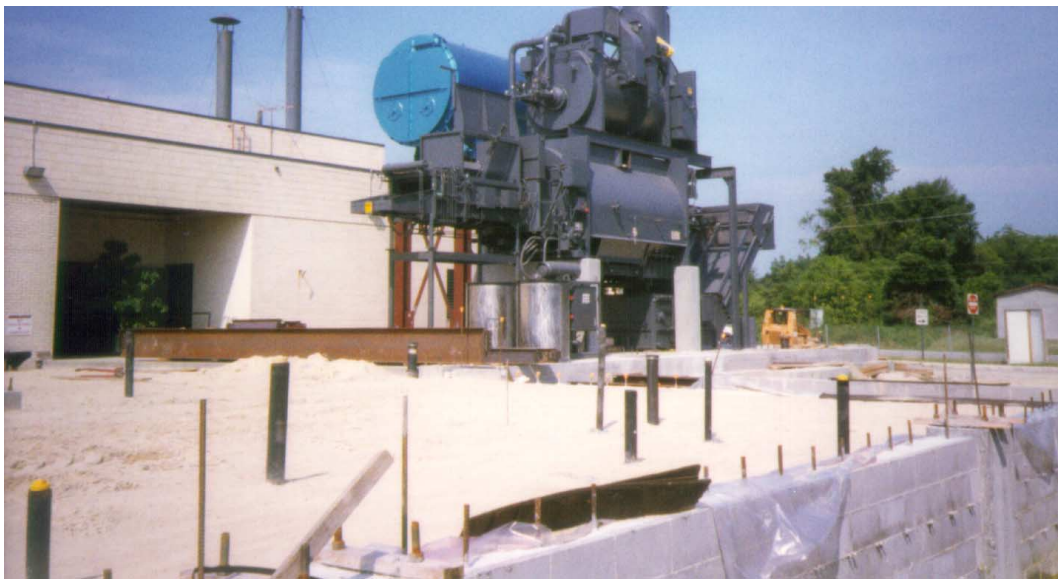


Fig. 11. Incineration emission control systems.

However, regardless of whether an incineration system is standard and proven or whether it is a new innovative design, there are usually stringent local or national requirements for large incineration system design, operation, performance, emissions, monitoring, authorization, and testing. As a result, it has become very difficult and costly to install new high capacity incineration facilities. Furthermore, even if environmental and health assessments unequivocally demonstrate that proposed incineration facilities present no risks to a community, public opposition can still be a difficult obstacle to overcome.



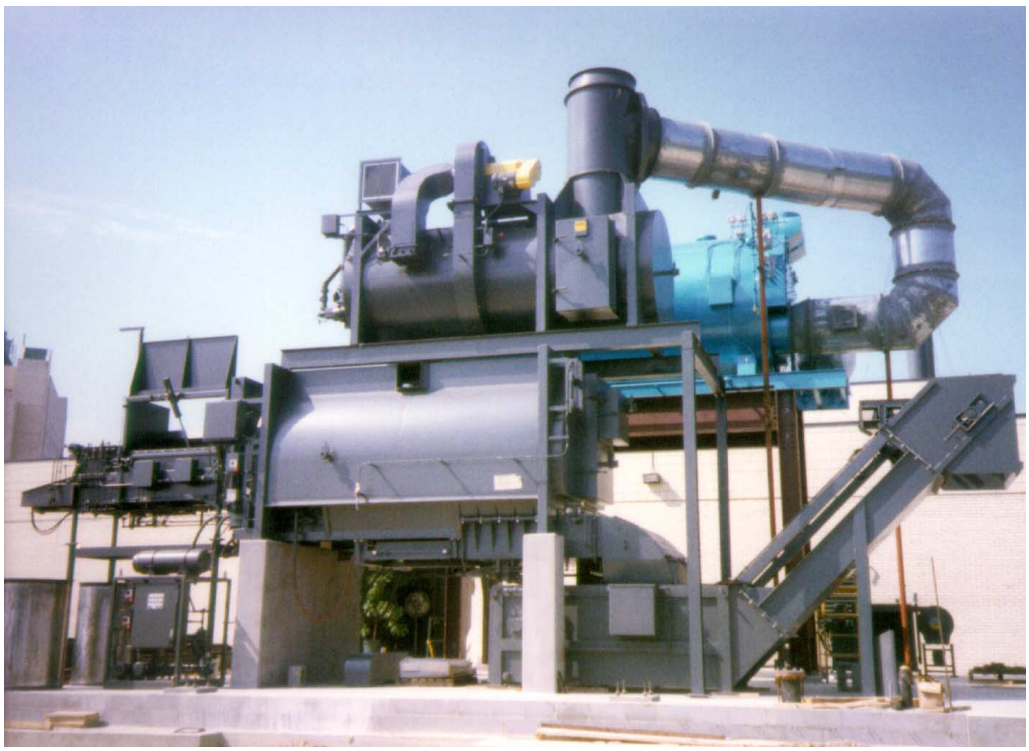


Fig.12. Biomedical waste incineration system under construction (USA).

Steam autoclaving

Autoclaving only deals with the biological hazard of the waste and not the radiological hazard (as an incineration). This method can be applied for sterilization of biomedical radioactive waste before storage for decay or further treatment. Waste contaminated with volatile chemicals (e.g. chemotherapy waste) or radionuclides such as ^{3}H, ^{35}S or radioiodines must not be autoclaved.

In an autoclave, steam is brought into contact with waste materials in a controlled manner and for sufficient duration to kill pathogenic microorganisms which may contaminate

the waste. Different types of autoclave systems are designed based on steam contact efficiencies and the volume of waste to be processed. Factors such as waste type and density, the type of packaging materials and the waste loading procedures used, directly affect steam penetration and the exposure times necessary for effective sterilization.

There are several advantages and disadvantages of using autoclave systems to treat biomedical waste. The principal advantages of these systems include low capital and operating costs, relatively small space requirements, and the simplicity of operations; these systems typically do not require excessive maintenance and repair. The principal disadvantages of autoclave systems are the relatively-limited system capacity, the possible need for special waste packaging and handling, and that special provisions must be implemented to prevent odor and drainage problems. In addition, the waste appearance remains essentially unchanged; needles, syringes, and other sharps are not destroyed. Waste transporters and landfills may not accept autoclaved waste even if it is proven to be sterile, because of its appearance. Autoclaving is not usually recommended as suitable for all biomedical radioactive waste types.

Microwave processing

Systems are available for treating medical waste through the use of microwave technology. The microwave units are generally available in two sizes; smaller units with a capacity of 100 kg per hour, and larger stationary units with a capacity of about 300 kg per hour.

In the microwave system, medical waste is fed into the unit via an automated loading system. The system is totally enclosed and runs under a slightly negative pressure to prevent aerosol emissions. The material is put through a shredder and sprayed with steam while it is being shredded. The unit may either be equipped with a steam generator, or steam may be supplied from an external source (such as a boiler). The waste then drops into a transfer hopper and an auger feeder moves the waste past a series of magnetrons or microwave generators. Microwaves are used to heat the waste to around 100^{o}C. The auger then discharges the material into a holding section. The temperature of the waste is monitored as it passes through the system to ensure that it is maintained at 100^{o}C. A second auger feeder is used to discharge the residue into a storage bin for ultimate disposal. Processing time is approximately 30 minutes, from start to finish.

The shredding process serves not only to disfigure the medical waste but to prepare it for distribution through the auger conveyor. Shredding reportedly provides up to an 80 percent volume reduction. Wetting the waste by steam injection facilitates the waste heat-up process because the water molecules absorb microwave energy much more efficiently. In the event of a breakdown, the waste in the hopper and other sections of the unit must be exposed to steam for approximately four hours to ensure disinfection. Microwave systems are of limited value and are not recommended for processing gross pathological waste or even small quantities of volatile biomedical radioactive wastes.

Dry heat

The biomedical radioactive waste is subjected to dry heat sterilization in a thermostatically controlled oven. This method achieves sterilization by high temperature coagulation of proteins, typically at temperatures of 160^{o}C. It is important that the entire load reaches the required temperature and it is maintained for one hour. This may require up to

three hours to sterilize a batch of waste. Quality control of the use of dry heat sterilization is achieved by the use of commercially available indicators, for example sterilizer control tubes, that undergo a permanent color change to prove sterilization conditions were obtained. These indicators should be placed in the middle of the batch of material to be sterilized. Dry heat sterilization is not appropriate if volatile radionuclides might be released.

6.3.3. Chemical treatment

Chemical processes are used to decontaminate biomedical waste through disinfection. Currently, most biomedical waste treatment systems use chlorine compounds, but other disinfectants such as mercurial compounds, phenolic compounds, iodine, alcohols, hexachlorophene, formaldehyde, as well as some combinations of these, can also be used.

Disinfection is a process used to control the biological hazard and possible risk of the spread of infection. Disinfection implies that the waste has been made safe by the removal or destruction of pathogenic microorganisms. However, some bacterial spores may not be totally destroyed by disinfection. Sterilization in contrast is the destruction of *all* organisms. A range of disinfection fluids or granules/powders may be used, e.g. 2% phenolic disinfectants, sodium hypochlorite diluted to 10^3–10^4 ppm available chlorine, powders or granules containing sodium dichloroisocyanurate. It is advisable to use disinfectants or undertake sterilization in a well ventilated area, as in some cases there can be resultant release of chlorine gas due to contact with acids, alkalis, oxidisable organic matter and EDTA.

Typical chemical processing systems utilize a shredding step in order to provide sufficient contact between the waste and disinfectants. The shredding step, in turn, disfigures the waste such that it is no longer visually offensive.

The biomedical waste is manually loaded onto an inclined conveyor belt which feeds a high torque, low speed shredder. The waste is then discharged from the bottom of this shredder into a high speed hammermill which granulates the waste. During both shredding stages, waste is continuously sprayed and saturated with a solution of sodium hypochlorite. The shredded waste is transported from below the shredders of both systems via a dewatering conveyor, which allows liquids to drain away from the solid residues. The solid residues, in turn, are deposited into collection containers or carts, and the free liquids are typically discharged following appropriate monitoring to a sanitary sewer. The solids, which are wet from the sodium hypochlorite, are held in the carts for “sufficient” time to provide an acceptable degree of disinfection. Afterwards, they are typically discharged into containers for off-site disposal provided they meet the clearance levels.

Reportedly, sodium hypochlorite contact time from the shredding stages and cart residence is sufficient for sterilization (sterilization is not guaranteed). To prevent airborne contamination from the process, a blower draws air from the discharge hoods of the feed and debris conveyors and maintains a negative pressure on the entire system. Exhaust air passes through a series of prefilters and special, chlorine-resistant HEPA filters before being discharged to the atmosphere. Typical systems have a capacity of 500 to 750 kg per hour.

The principal advantages of chemical disinfection systems combined with shredding are that they are relatively simple to operate, provide a substantial volume reduction (up to 80 percent) and alter the waste appearance and form such that all items are no longer visually offensive. These combined treatments are suitable for processing most types and forms of

biomedical waste, except chemotherapy waste, and pathological remains. Biomedical radioactive wastes are not usually processed in this manner unless the radionuclides involved have short half-life and the material can be stored for decay to acceptable levels prior to processing. Otherwise the end result is radioactively contaminated hazardous chemical waste and contaminated equipment.

6.4. ON-SITE TREATMENT

6.4.1. General considerations

There are a number of advantages for making the individual health care facility, clinic or user responsible for "complete" treatment of radioactive materials used on-site:

— There are incentives for carefully planning a clinical programme. These include sound practices like waste prevention and minimization, or treatment at source which is more evident to the user;

— It is easier to retain full traceability of the waste;

— The labeling and record keeping requirements can be more easily met;

— Transport is minimized, so waste packaging demands will not be as great, especially if the waste is disposed of within the boundary of the premises where it is produced;

— The generating establishment retains control and responsibility until the waste can be discharged at clearance levels, or a centralized facility becomes available.

An on-site strategy can be a fully acceptable and cost-effective method for the treatment of biomedical radioactive wastes, but success of the operation is dependent upon the availability of the necessary technology and local expertise.

Potential disadvantages of an on-site strategy should also be recognized. These become more pronounced as greater use is made of radioactive materials in medicine.

The primary disadvantage is lack of standardization, as each institution will develop its own preferred treatment strategy. While this is acceptable and cost-effective for some users, for others the system may eventually become unmanageable. Potential disadvantages are:

— Practices may lack the rigor and quality assurance demanded from a centralized strategy. State of the art practices that could be realized in a centralized strategy may be financially or technically unattainable by individual institutions;

— Methods of record and document keeping may be inconsistent;

— Waste handling, treatment, and conditioning facilities may be duplicated unnecessarily.

6.4.2. Treatment of gaseous waste

Gaseous wastes are of minor concern from biomedical use of radionuclides and rarely necessitate specific management. xenon-133 and krypton-81^{m} are used in diagnostic imaging for assessment of regional lung ventilation. Since they are noble gases, they are difficult to trap and are often released to atmosphere via a pipework exhaust system. It is essential to ensure that there is no possibility of re-entry of the released gases back into the building through open windows.

In some hospitals, xenon-133 is exhaled during the diagnostic test and is trapped on a charcoal filter. These filters require subsequent management and disposal. They are usually stored to decay and disposed of at clearance levels.

The use of ^{99m}Tc-DTPA (diethyl tetra pentaacetic acid) lung aerosol is increasing in use. This procedure does not generate gaseous waste, but results in some solid waste production, e.g. gloves, mouth swab, and excretion of radioactive urine.

The use of volatile radionuclides in a fume cupboard or extraction cabinet, such as radioiodines or tritium, results in release of vapors which are usually trapped on a charcoal or HEPA filter. The filters are changed periodically and are stored to decay prior to disposal in the incinerator at clearance levels.

6.4.3. Treatment of liquid wastes

Most of the radionuclides used in nuclear medicine departments are short lived and are of low or medium concentration. The liquid residues following patient injection can be disposed of after an adequate period of decay storage so that the radioactivity reaches the clearance level. The residues can then be directly discharged into the drainage system.

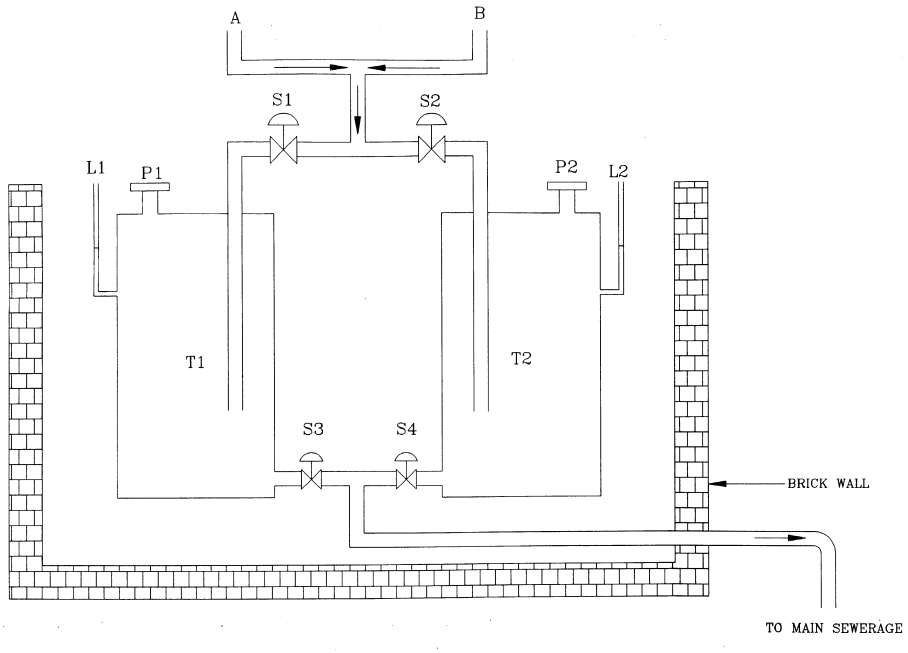
The vast bulk of medical discharges are in the form of patient urine. In many countries, urine is discharged directly to a sewage system without any delay or pretreatment, despite the fact that there may be relatively high radionuclide activity. This practice may not always be adequate to reduce the activity of the waste to acceptable levels by dilution at the final discharge point. It is essential to assess the environmental consequences of such actions before introducing such a practice.

Hospitals administering large quantities of ^{131}I for treatment of thyroid carcinoma should consider the provision of delay tanks for storage and safe disposal of radioactive waste resulting from patient excretion [17, 18]. It is suggested that the drainage outlet of the therapy ward should be connected to a delay tank of appropriate capacity to allow the activity to decay for an appropriate period (which may correspond to 6–8 half-lives) prior to discharge into the sewage system. This will ensure that about 1% of the initial activity remains in the tank at the time of release into the public sewage system.

Figure 13 shows a typical design of a dual tank delay system. The optimum capacity of each delay tank should be decided on the basis of anticipated daily release of effluents from the ward. However, two tanks, each with a capacity of about 5000 liters may be adequate for a two bedded isolation ward. The delay tanks should be leak proof, corrosion resistant, and should have smooth surfaces inside. The outlets of the tanks should be at a higher level than that of the main sewerage line to avoid back flow of effluents.

One tank at a time should be used for collecting effluents from the therapy ward. The tanks should have a warning device which operates when the tank is almost full so that the effluent outlet of the patient ward may be manually or automatically connected to the second tank. The collected and decayed contents of the first tank should be sampled (after an appropriate storage period) before discharging directly to the main sewage system. In some cases, ^{131}I contains fission product impurities of longer half-life which can delay clearance. However, it is necessary to ensure that the average monthly concentration of the activity at the

discharge point does not exceed the limit laid down by the relevant regulatory authority. This method of waste disposal is currently being followed in India and has concurrence of the regulatory authority [17].



P1, P2 — Provisions for collecting samples/inserting probe for estimating radioactivity concentration;
S1, S2 — Inlet gate valves; S3, S4 — Outlet gate valves;
L1, L2 — Fluids level indicators;
T1, T2 — Storage tanks (preferably below ground level);
A,B — Outlets of toilets of ^{131}I therapy patient wards.

FIG. 13. Typical design of a delay tank prior to discharge of radioactive waste from Iodine-131 therapy wards.

In France, a dual system toilet has been developed which provides liquid waste minimization by separate collection of urine, with associated minimal use of water for toilet flushing. Under these circumstances, dual tanks of 500 liter capacity may be sufficient for an optimized storage of liquid for decay.

Provisions for periodic maintenance, repairs and area contamination checks in and around the delay tank system should be mandatory. In addition, adequate provision should be made for sanitary control of the tanks by appropriate disinfection techniques using chemical methods. Brick/concrete wall structure of appropriate thickness around the delay tank system will protect the public from undesired radiation exposure and contain the radioactivity in case of accidental leakage. Suitable security should be provided to prevent unauthorized entry to the delay tank site.

Although in India, delay tanks for radioiodine therapy suites is common practice, this situation is not universal. In the United States and UK, delay tanks have not yet been introduced to any great extent, although they are currently being considered in the UK at selected hospitals where there is a proven environmental impact due to the increasing discharge of radioiodine from patient treatments and where minimal dilution of the discharged effluent subsequently occurs.

In Northern Ireland, the radioactive urine from radioiodine patients is collected and stored in 2 liter glass bottles. This liquid waste is held to decay for three months prior to discharge into the public sewerage system. This practice is also common in the USA.

Small amounts of liquid radioactive wastes contaminated with relatively long lived radionuclides may be collected and transported to a centralized facility for evaporation or direct solidification in concrete although this is not a common practice. When the quantity of the waste is small, then it may be conditioned in concrete or gypsum at the producer's facility. When the liquid wastes contain a lot of organic compounds, they are usually absorbed on silicate material (e.g. "Vapex") and fixed in concrete for final disposal. This method may also be used for high activity or longer lived radionuclides in liquid scintillators. More information on treatment and conditioning of this type of waste can be found in Ref. [10].

6.4.4. Treatment of solid waste

Solid waste generally contains relatively low levels of radioactivity when compared to liquid wastes. Solid biomedical waste consists mainly of general trash, which includes protective clothing, plastic sheets and bags, gloves, masks, filters, overshoes, paper wipes, towels, metal and glass, hand tools and discarded equipment (see Section 2).

Some of the treatment processes described in Section 6.3 can be used for solid biomedical radioactive waste, but the most preferable method is incineration.

Solid radioactive wastes including carcasses and excrements could be incinerated on-site in a facility similar to that shown in Figs 10 and 11. If the activity of the ash does not exceed clearance levels, then it can be disposed of in a landfill (see Section 8). In exceptional cases when this practice is not appropriate for the given type of incinerator (e.g. when the biomedical waste is incinerated at a plant that predominantly burns waste from the nuclear fuel cycle), the wastes may be chemically neutralized and fixed in concrete for final disposal. This type of practice is likely only to occur at centralized facilities.

A simple low capacity incinerator has been developed and tested in Russian Federation for on-site incineration of low level biomedical radioactive waste. This incinerator is based on application of specially designed powdered metal fuel that is intermixed with waste in a proportion of 20% fuel and 80% waste [19]. The incinerator consists of an incineration chamber with fire grate where the waste is burned. It operates periodically at temperatures of about 700–1000^{o}C. The ash/slag residue after combustion of the waste is collected and cemented or disposed of at clearance levels, depending on the radionuclide activity remaining.

Other possibilities for treatment of solid, biomedical radioactive waste are maceration/pulverization, mummification, dissolution in acids, bases or hydrogen peroxide. These, and other treatment and conditioning methods applied for waste from a range of nuclear applications [20] may also be considered for processing of some kinds of biomedical radioactive waste.

6.4.5. On-site immobilization of spent sealed sources

On-site immobilization of spent sealed sources should be considered in order to provide safe conditions for long term storage or transportation. Management of spent sealed sources can involve an increased radiation hazard, therefore special care needs to be taken

during immobilization. On-site immobilization of spent sealed sources usually is provided by cementation in 200 L drums. For this purpose, containers with sources are placed inside a prefabricated drum as shown on Fig. 14. Original hole in concrete is filled with cement mortar after placement of containers with sources. In the case of ^{226}Ra sources it is necessary that the sources are conditioned in a "retrievable way" [2] allowing reconditioning in the future if required to meet any future acceptance criteria for deep geological disposal of long lived waste. Leakage of gaseous ^{222}Rn which is a product of ^{226}Ra decay should be prevented. Radium sources should not be mixed with other spent sealed sources with shorter life time as this would make future waste management very complicated.

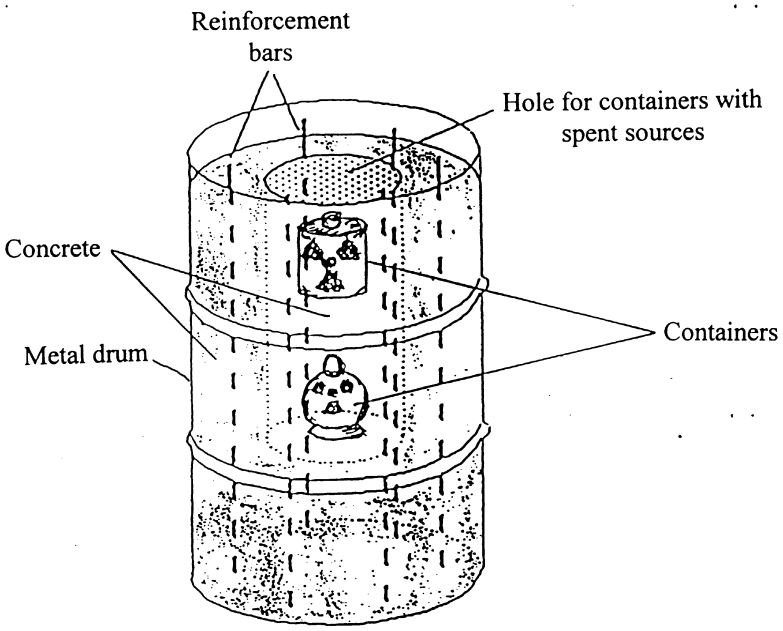


FIG. 14. Immobilization of spent sealed sources in a metal drum.

6.5. TREATMENT OF MEDICAL WASTE AT CENTRALIZED FACILITIES

6.5.1. General consideration

In some countries, biomedical radioactive waste is managed at centralized facilities. Centralized treatment is more commonly used for medical research wastes and spent sealed sources from medical treatments.

Generally solid long lived, non-combustible radioactive wastes are collected from users for treatment at centralized facilities. Spent sealed sources are collected and transported to centralized facilities where they are conditioned in preparation for storage and disposal. Gaseous or liquid radioactive wastes from biomedical applications of radionuclides rarely require management at a centralized facility. Exceptions to this would be where no on-site incineration facilities existed and there was a requirement for incineration of organic scintillation fluids (at a centralized incineration facility).

Centralized facility treatment is appropriate for countries that have some infrastructure for manufacturing and distributing radioactive materials for widespread use in medicine. However, in some instances it may also be advantageous for other countries, particularly if

longer lived radioisotopes are involved. Individual producers of biomedical radioactive waste may not have the necessary incentives, available technology, or expertise in waste management to be able to develop a complete and satisfactory waste management system. If the treatment of small quantities of waste at individual facilities is not cost effective, it may be appropriate to consider having a centralized waste management facility where the necessary expertise, infrastructure and quality assurance capabilities can be developed.

The centralized concept of management of biomedical radioactive waste requires to define the responsibilities of the waste producers and the receiving facility as follows:

— The waste receiving facility establishes the waste acceptance requirements which are likely to include physical, chemical, biohazardous and radiological characteristics, as well as the actual quantity of the waste;
— The producer would be responsible for characterizing each waste to ensure that it is in accordance with the receiver's waste acceptance requirements, and in full compliance with regulations relating to both the biological and the radiological hazards;
— The waste receiving facility would assume complete responsibility for subsequent management of wastes, including any necessary verification of data provided by the waste producers. The receiving agency usually reserves the right to refuse to accept (and possibly return to the producer) any waste which does not meet the pre-arranged acceptance criteria;
— The receiver would be responsible for establishing the costs associated with proper management of wastes in full compliance with regulatory requirements and would be able to recover these costs by an appropriate charging scheme.

In contrast to the disadvantages of an on-site strategy for management of biomedical radioactive wastes, as detailed in Section 6.4.1, there can be advantages in utilizing a centralized waste management facility:

— a more uniformly characterized waste form is packaged for final disposal;
— the system can be more rigorously controlled with all the individual waste producers working to the same protocols;
— the larger central facility should be able to achieve more cost-effective use of technology, i.e. economy of scale;
— by recovering its costs from numerous waste producers, a central facility can afford to use more advanced technologies.

6.5.2. Treatment of solid waste

Solid medical radioactive wastes may be treated using different methods depending on their nature. All methods mentioned above in Section 6.3. may be applied on a larger scale at a centralized facility for the treatment of solid biomedical radioactive waste. Usually at a centralized facility only a few technological processes are actually applied for the treatment of solid biomedical waste with the principal process being incineration. Typical incinerator design for centralized treatment of biomedical radioactive waste is shown on Fig. 15. Waste is loaded into the feed hopper and a hydraulic ram pushed it into the primary static combustion chamber of the incinerator where initial combustion is occurring. Complete burn-out is achieved in the rotating incinerator kiln, where gas jets raise the temperature to 900^{o}C.

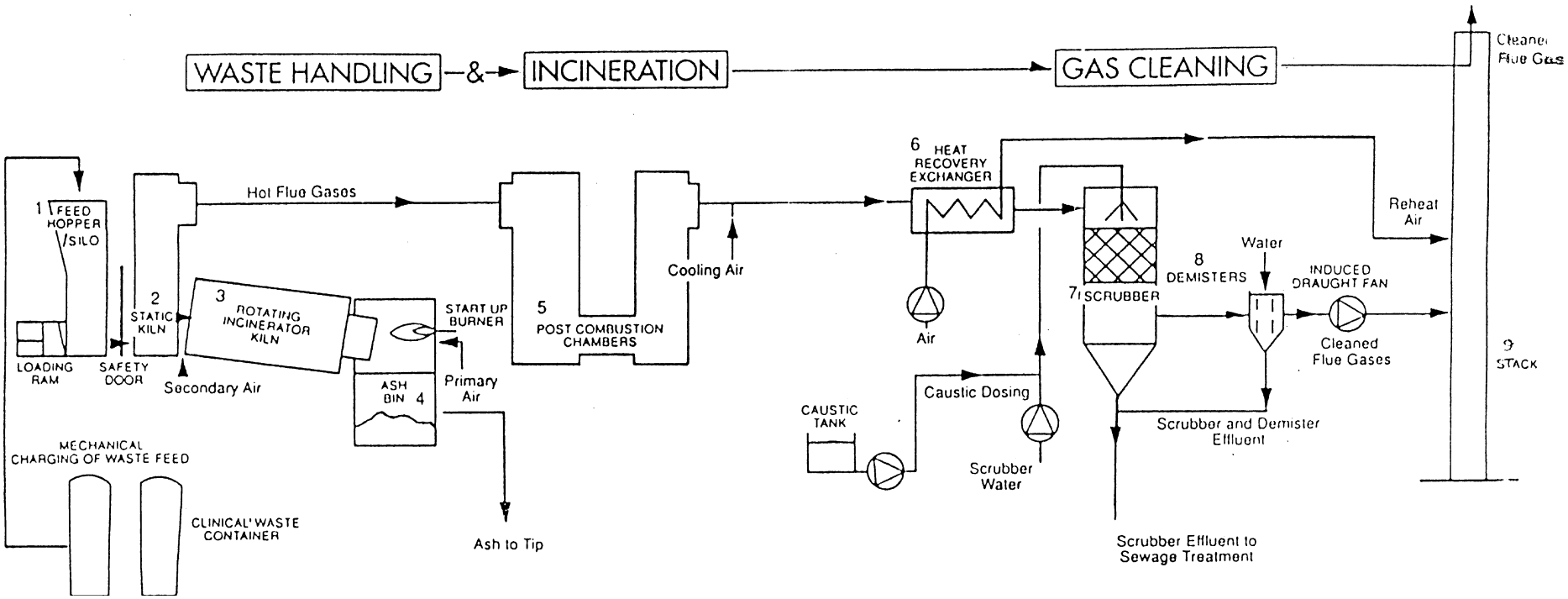


FIG. 15. Process flow diagram for an incinerator used at a centralized facility.

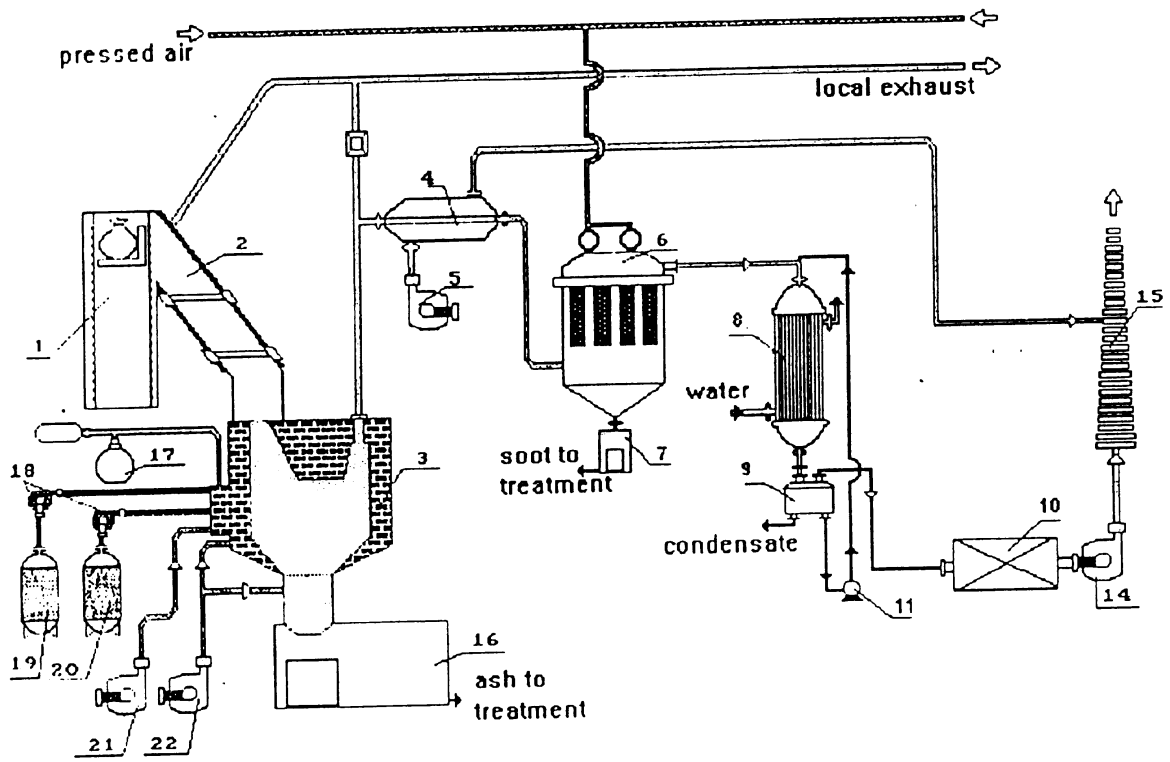
The secondary upper chamber has the job of destroying the organic components which are in the fumes which leave the lower chamber. An air/gas burner fires into this chamber and raises the temperature to a point where any hazardous organic materials are destroyed (1100^{o}C). Combustion gases from burning waste are typically retained in the secondary chamber for periods ranging from 0.5 to 2.0 seconds. These time and temperature conditions are more than adequate to provide virtually instantaneous destruction of all microorganisms and organic components of waste. The hot gases from the second chamber then flow into a boiler. The total heat outflow from one incinerator unit is approximately 2 MWt. The cooled down fumes then pass into a wet scrubber. Here, a caustic solution is sprayed into the gases to remove any remaining particulate materials and to neutralize of acid gases. A clean effluent passes to the atmosphere via the stack. The incinerator is provided with waste heat recovery unit for transferring part of waste heat to stack to prevent visible steam plume.

This type of incinerator may treat solid as well as small amounts of liquid radioactive wastes that are collected at various medical centers and research institutes. In some countries, medical waste is incinerated together with waste collected from a range of different medical research and industrial establishments. One example of such a facility is the central treatment facility “SIA Radon” in Moscow (Fig. 16). This facility has an excess-air incinerator with a ceramic combustion chamber and secondary post-combustion chamber with gas cleaning system. The capacity of the incinerator is 100 kg/h for liquid waste. The specific activity limits for acceptance of solid waste contaminated with β-radionuclides is 3.7 MBq/kg and for α radionuclides not higher than 0.37 MBq/kg. The specific activity of liquid radioactive waste containing β-radionuclides is not higher than 37 kBq/kg and for α-radionuclides, less than 3.7 kBq/kg. The content of chlorine and sulfur in the waste to be burnt is limited to 5% by weight. The incinerator has a gas cleaning system which consists of heat exchangers, coarse and fine filters and a cooler and condensate collector. The average concentration of ^{137}Cs in the stack discharge is 10^{-16} Ci/m^{3}. Three products are produced from the incineration operation — ash, soot and condensate. The average radionuclide partitioning is 90–95% for ash, 1–5% for soot and 0.1–2.0% for condensate. The average volume reduction factor for solid waste is 60–80, while for liquid waste is 600–800.

Another treatment method used at a central facility is compaction. Solid medical radioactive waste which *is not biologically hazardous* can be subjected to a considerable volume reduction through compaction. Solid medical radioactive wastes are fed into a compactor together with their containment, or prior to compaction are overpacked into multilayer (plastic or paper) bags or into metal drums. After compaction the waste is disposed of with or without additional conditioning by cementation. Figures 17 and 18 show a typical in drum compactor and crusher used at a centralized facility for the compaction of solid radioactive waste.

6.5.3. Conditioning of secondary waste

The treatment of biomedical radioactive waste may give rise to the production of secondary waste streams such as contaminated off-gases, liquids and solid materials or equipment components. At well designed waste treatment facilities secondary wastes can be treated and conditioned without problems by current available processes. Practically the same treatment principles are applied for the treatment and conditioning of secondary waste as for the gaseous, liquid and solid primary waste.



1 — lift; 2 — loading unit; 3 — furnace; 4,8 — heat exchangers; 5,12,-14 — fans; 6 — high temperature filters; 7-soot collector; 9 — condensate tank; 10 — HEPA filter; 11,18 — pumps; 15 — stack; 16 — ash removal unit; 17 — ignition system; 19 — fuel tank; 20 — liquid waste tank; 21,22 — air pumps.

FIG. 16. Industrial plant for the incineration of radioactive waste from medical applications at "SIA Radon", Russian Federation.

As an example, when incinerating biomedical radioactive waste, secondary radioactive waste in the form of ash residue is produced. Some radionuclides from the primary waste can be almost completely retained in the ash or lime residues (Table III) [21–23]. In this case, the ash may have much higher radionuclide concentration per unit volume than the original waste and so is subject to additional conditioning by cementation and packaging prior to disposal [24].

TABLE III. RETAINED RADIOACTIVITY IN ASH AND LIME RESIDUES

Radionuclides	% activity	
	ASH	LIME
^{123}I, ^{125}I, ^{131}I	1%	65%
^{22}Na, ^{32}P, ^{51}Cr, ^{57}Co, ^{59}Fe, ^{67}Ga ^{111}In	60%	20%
^{35}S	25%	10%
^{14}C, ^{3}H*	-	-

*When ^{3}H is burnt in an incinerator with a wet gas cleaning system, up to 20% of incinerated activity may be recovered as tritiated water.

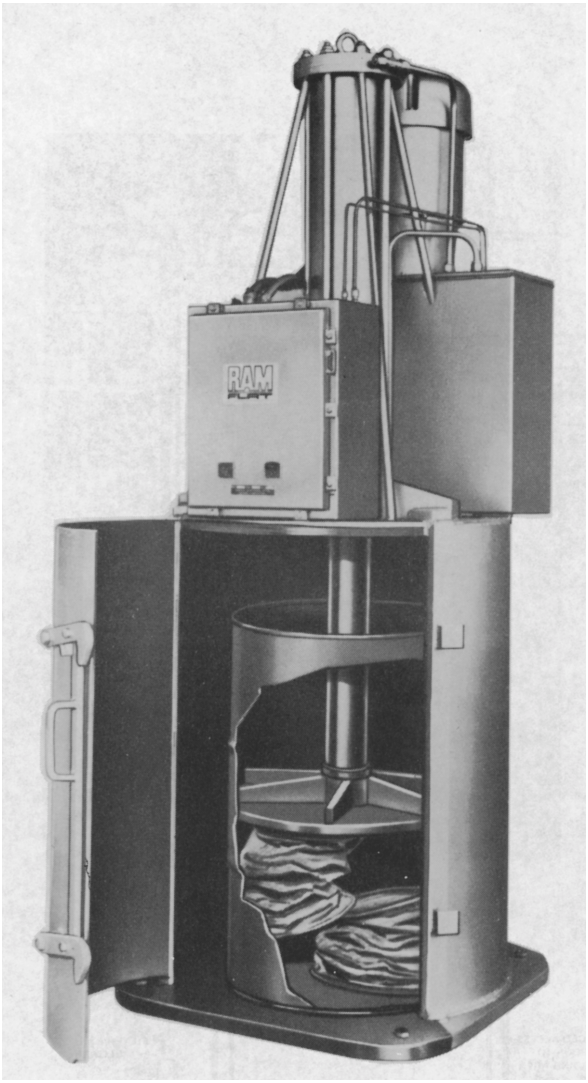


FIG. 17. In-drum compactor (USA).

Fig. 18 Drum Crusher (USA).

More commonly, the ash and lime residues are disposed of at clearance levels or at levels specified by the regulatory authority.

Secondary liquid radioactive waste from biomedical origin may also need to be cemented or subjected to other conditioning method (bituminization, vitrification). These conditioning methods are described elsewhere [24–27]. Existing gas-purification systems at centralized facilities provide gas purification without production of secondary gaseous radioactive waste.

Storage, transport and final disposal of conditioned waste is identical to that of non biomedical waste origin.

7. MANAGEMENT OF SPENT SEALED SOURCES FROM BIOMEDICAL APPLICATIONS

7.1. GENERAL

Sealed radiation sources become surplus when:

— the activities of the sources have decayed to the extent that they are no longer suitable for their original purpose,

— the clinical procedure or experimental programme using the source is completed or discontinued,

— the source develops a leak, or

— the source apparatus becomes outdated, or difficult to operate.

Spent sealed sources present a unique situation in the management of biomedical radioactive waste since regulatory organizations may impose strict conditions on their ultimate disposal. These sources typically do not have additional hazards beyond that posed by the contained radionuclide. Exceptions are in the case of sources that are shielded with heavy material which may pose a physical hazard, sources that are found to be leaking or sources which have previously been implanted in a patient that are returned to storage without proper sterilization. Good management practice also dictates determining disposal methods at the time the sealed source is purchased.

Sealed sources are high integrity capsules each containing a small mass of a specific radioisotope in a concentrated form. The isotope in each case has been chosen for a specific application and the radiation level from the source is usually intense. A very high degree of containment of the radioactive material is provided in the design of the capsule. This facilitates handling in transport and use. The activity of the source depends upon the application and varies from calibration sources of a few MBq to powerful radiotherapy sources containing TBq levels. The higher activity sources are usually double encapsulated in a corrosion resistant metal such as stainless steel. Radioisotopes are normally gamma sources but may also include beta calibration sources or alpha sources used as anatomical markers (e.g. ^{241}Am).

Users may have the following management options to consider:

— transfer the source to another authorized user for application elsewhere at the current activity level;

— return of the spent sealed source to the original supplier;

— store sources containing radionuclides with short half-life for decay;

— collect and store sources in an interim facility until a conditioning facility is available;

— conditioning of the sealed sources at a centralized facility for final disposal.

The option selected for a particular sealed source will depend on the variety of relevant factors including activity, radioisotope content, terms of the purchasing contract and physical condition of the source [3]. A flow chart for management of spent sealed sources is given in Fig. 19.

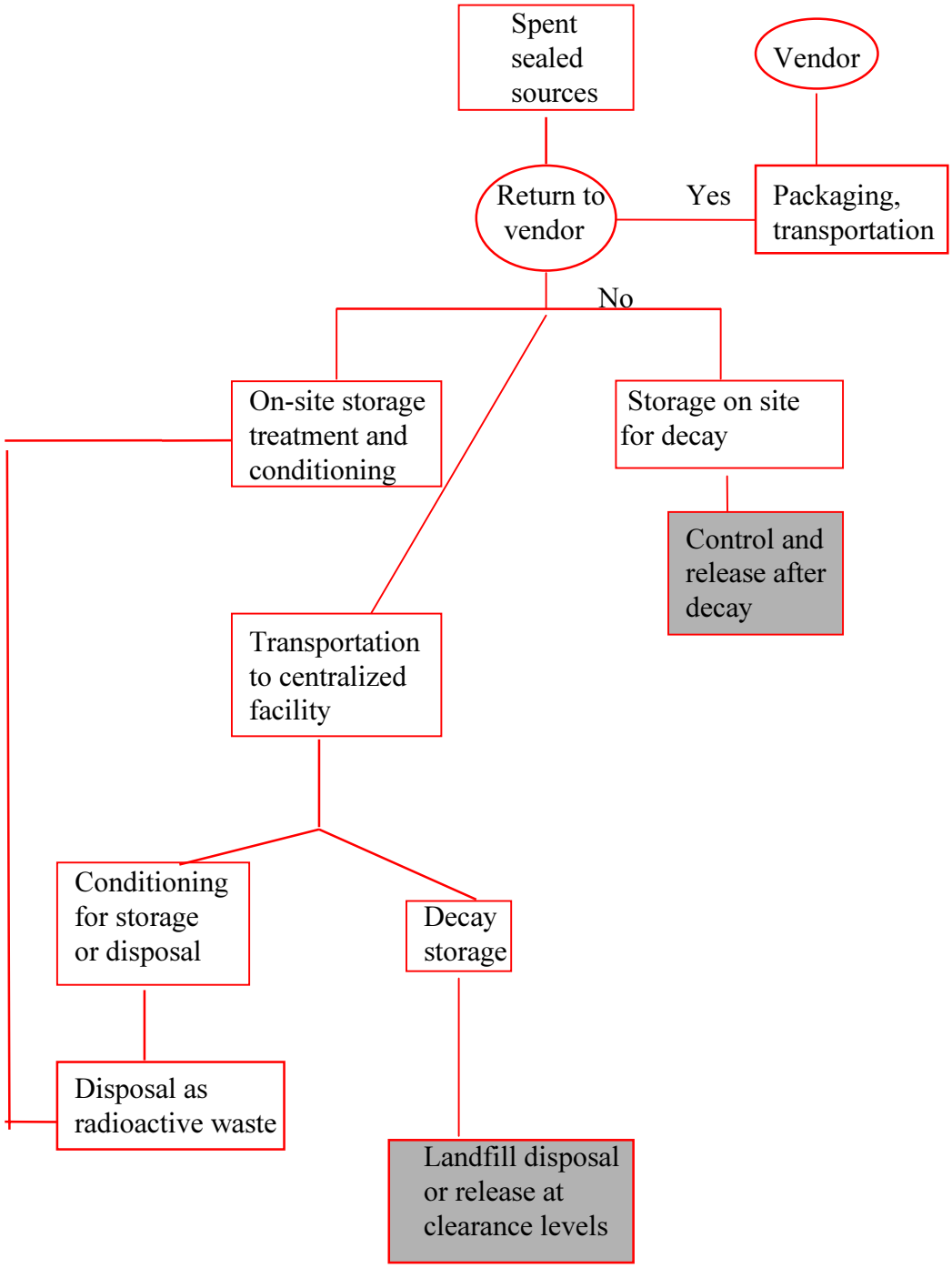


FIG. 19. Example of a flow chart for managing spent sealed sources.

It should be kept in mind that the cost of disposal of some spent radiation sources having very low activity may be greater than the original cost to procure the source. Returning the source to the supplier may not always be an option. Where it is, the return to the supplier may often be delayed due to problems in obtaining the appropriate approval or transport container.

The costs and other difficulties associated with spent sealed source disposal may give rise to a proliferation in the number of sources retained at the healthcare facility. A concern then arises in maintaining adequate control, security and documentation of all the stored sources.

It is important that each facility maintains an up to date and readily available inventory of sealed services.

7.2. SECURITY AND PHYSICAL PROTECTION

The risks associated with the spent sealed sources, and the precautions which are necessary vary widely. They depend on the source type, form, application type, existing condition of the source, physical characteristics, the radionuclide, the activity and the quantity. There have been numerous recorded incidents where spent sealed sources have ended up at scrap metal merchants, resulting in contamination and substantial public exposure. Security and physical protection of spent radiation sources can be a very serious problem for healthcare facilities. General security of the facilities is not as strict as normally found in nuclear centers because access to the hospital is required by patients, visitors and medical staff.

During the time that the sealed source is stored, special attention must be given to the following aspects:

— all available technical information regarding the source such as source type, source strength, date of production, etc. must be reliably preserved;

— physical security such as security locks, alarm systems, heavy packages, etc. must be assured and regularly inspected;

— scheduled preventative maintenance should be performed on buildings, locks and handling equipment;

— a list of all the routine checks should be maintained and performed;

— an operator=s training programme should be implemented, with refreshing training of personnel provided periodically. Records of operator training should be kept.

— where prolonged storage is anticipated, periodic wipe tests should be performed at intervals compliant with regulatory requirements.

The results of the activities of inspection and maintenance should be reported to the regulatory authority on a routine basis.

Sealed sources are usually very high integrity cylinders, needles, seeds or grains. A high degree of containment of the radioactive material is provided in the physical design of the source. A robust construction of the source is necessary for both the transport and use. Administrative procedures and proof of integrity requirements should be implemented by appropriate tests. These will be required before the source is transported or transferred to another facility. A dose rate meter capable of measuring high activity gamma radiation should be available.

7.3. COLLECTION AND SEGREGATION

The subsequent handling of spent sealed sources is made easier if they are collected and segregated at the point of origin. Each source category should be collected separately. The following categories may be considered when establishing a segregation system:

— Small sealed sources used for calibration, typically <4 MBq activity which may be disposed of without further treatment in a repository for low and intermediate level waste;

— Sealed radiation sources >4 MBq which after treatment and conditioning can be disposed of in a repository for low and intermediate level waste depending on local authorities;

— Sealed radiation sources, with activities exceeding those acceptable for disposal in a repositori for low and intermediate level waste;

— Sealed radiation sources of long half-life and other sources which are typically returned to the vendor/supplier or to a centralized waste management facility.

The categorization of spent sealed sources is determined by national waste management policy, and depends on the availability of facilities for treatment, storage and disposal. The complexity of the segregation programme for spent sealed sources will depend on the number of sources in each category and may be radionuclide specific.

7.4. TRANSFER TO ANOTHER USER

A sealed source is procured with an original activity level appropriate to a specific application. When the source activity is no longer suitable for the original application, there may still be sufficient radioactivity to allow them to be used for another purpose. This may especially be the case for the high activity ^{137}Cs and ^{60}Co sources. Sources no longer of use for clinical therapy may well be useful in other applications requiring lower levels of activity. Transfer of sources to other approved users within or outside the national boundaries of the country offers economic advantages in both source procurement and final waste management. The net effect being a reduction in the number of sources which have to be purchased, managed in use and finally consigned to disposal [3]. It is essential that all relevant paperwork is transferred to the new user along with the source so that accurate records can be made in their source inventory.

7.5. RETURN TO VENDOR/SUPPLIER

In most situations it is preferable to return the spent sealed source to the vendor or supplier. This is best arranged as part of the original purchasing contract of the source. However, it is recognized that this may not be economical or practical in all cases. The latter may arise when the original vendor or supplier is no longer available or able to accept the source or where transport of the source to the point of origin is not possible. In such circumstances, it is preferable if management of the spent sealed sources is carried out at a centralized facility.

Returning the source to the original supplier may provide the manufacturer with the opportunity to recycle the radioactivity contained in the spent sources as it is frequently economically attractive to recover the radioactive component for incorporation in new sources. Disposal of the spent sealed source to a different supplier is another option for consideration. Many institutions in different countries routinely refurbish spent sources for economic reasons.

7.6. STORAGE AND IMMOBILIZATION

Storage may be defined as the placing of the source in a system with the intention of retrieving the source in the future for another purpose or further treatment. Storage of the source may include some type of immobilization such as embedding or encapsulation of the source in a drum with concrete, provided the sources are still retrievable and remain intact. All storage systems require secure facilities such as safes, strong-rooms or concrete bunkers.

Storage capacity is necessary for short-term storage of sources which cannot be expected to decay in a reasonable time, prior to them being transferred to a central storage facility. On-site interim storage periods should be kept as short as possible to take advantage of the higher security arrangements of centralized storage facilities. Where centralized facilities are not available, the spent radiation sources may have to be stored for many years. In this case, special emphasis on the integrity of the package, appropriate physical protection and record keeping are required.

Decay storage of spent sealed sources with short half-life should provide sufficient time for the activity to decay to such a level that they can be considered as inactive material and disposed of as non-radioactive waste. If the decayed spent sealed sources go to public waste areas such as a landfill, the competent local authority must be sure that the residual activity is below clearance levels and that all labeling has been removed.

7.7. CONDITIONING OF SPENT SEALED SOURCES AT CENTRALIZED FACILITIES

At a centralized facility where a large number of sources are collected there are usually two options for immobilization. The first way is similar to that described above where sources in their original containers are immobilized in metal drums or prefabricated concrete tubes. Another option is when sources are unloaded from their original containers and immobilized in special container for storage or disposal.

Some countries where the number of spent radiation sources is very large, (e.g. Russian Federation, South Africa, parts of eastern and central Europe) adopt another option for conditioning these sources. The spent sources are unloaded from their original containers and are transferred into shallow boreholes specifically designed for long term storage In situ conditioning of the sources by grouting with cement or low melting point metal alloys is practiced at some facilities.

7.8. TRANSPORTATION

Sealed sources being returned to a vendor/supplier or sent to a centralized storage facility should be packaged and shipped in the original shipping container if available, e.g. a lead container with overpack. Arrangement for transportation should be made in accordance with national regulations and established international standards.

Prior to transportation of a spent sealed source, it is essential to verify that the source is not leaking and that the integrity of the shielding will be guaranteed throughout transport. Appropriate paperwork containing all relevant technical information should be available, including the results of the wipe-test or other integrity test as appropriate. Should the source be found to be leaking, further containment of the source is required to prevent contamination of the transport container. Further tests to verify that the source has not been subject to damage in transit are necessary upon receipt at the centralized facility.

Shipments of spent sealed sources should follow the standards which are provided in IAEA transport regulations [15]. This document includes details of general safety principles, activity limits, testing requirements for package types, storage in transit and inspection procedures.

8. DISCHARGE OF WASTES BELOW THE CLEARANCE LEVELS TO THE ENVIRONMENT

8.1. THE CLEARANCE CONCEPT

Sources and practices may be removed from the system of regulatory control provided the radiological impact of these practices/sources is sufficiently low as not to warrant any further control. Such removal of sources and practices from regulatory control is called “clearance” [8].

The basic criteria for determining whether sources and practices should no longer be subject to regulatory control are identical to the exemption criteria set out in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources [28]. They are as follows:

(a) the radiation risks to individuals caused by the practice or source should be sufficiently low as to be of no regulatory concern;

(b) the collective radiological impact of the practice or source be sufficiently low as not to warrant regulatory control under the prevailing circumstances; and

(c) the practices and sources be inherently safe, with no appreciable likelihood of scenarios that could lead to a failure to meet the criteria in (a) and (b).

A practice or a source within a practice may be exempted from regulatory control (or cleared) without further consideration provided that the following criteria are met in all feasible situations:

(i) the effective dose expected to be incurred by any member of the public due to the practice or source is of the order of 10 μSv or less in a year, and

(ii) either the collective effective dose committed by one year of the performance of the practice is no more than about 1 man.Sv or an assessment for the optimization of protection shows that exemption is the optimum option [8].

8.2. CLEARANCE LEVELS

Setting clearance levels for the discharge of radionuclides is a difficult process. IAEA-TECDOC-1000 discusses the clearance of materials resulting from the use of radionuclides in medicine, industry and research [8]. This document is a considerable step forward after a review period extending over the last 10 years. It presents both numerical values and a number of conditions to be considered when establishing particular clearance levels, such as:

— No appreciable likelihood of scenarios that could lead to a failure to meet the criteria (i) and (ii) discussed above in Section 8.1;

— It is assumed that radionuclides are more or less uniformly distributed throughout a moderate quantity of the material;

— If more than one radioactive waste producing establishment is discharging into the same environment, the combination should be taken into account;

— There may be other non-radiological reasons for not granting a clearance, for example if an appropriate quality assurance system is not in place;

— A summation rule should be applied to a mixture of radionuclides

$$\sum_{i=1}^{n} \frac{C_i}{C_{Li}} \leq 1$$

— where C_i — the proposed release rate in Bq/a or concentration Bq/g of radionuclide i in the waste, C_{Li} — the limiting clearance release rate, Bq/a or concentration Bq/g of radionuclide i in the waste, n — the number of radionuclides in the mixture.

— If larger quantities of materials are involved, the clearance levels might no longer be appropriate.

When the predicted exposure from released material is not certain to be trivial, then disposal at a specialized repository must be considered.

Many countries have previously defined clearance levels for radionuclides which are based on annual limits of intake (ALI) or fractions of ALI or refer to statistically significant differences from background activity. It is the responsibility of the regulatory authority to define clearance levels and site specific discharge authorizations.

The recent European Commission approach to the exemption of radiation sources from regulatory control [9, 29] extends the exemption concept to non-nuclear fuel cycle materials

and introduces a new clearance approach. These regulations should be mandatory in all European Member States by May 2000.

In the revised Basic Safety Standards Directive, the European Commission sets minimum requirements for conditions where reporting, licensing, and prior authorization are not needed. The Annex to the Directive contains a list of nuclides with values of quantities (Bq) and concentrations of activity per unit mass (kBq/kg) that are not to be exceeded. More detailed information on existing practices on exemption in the European Community countries can be found in Reference [9, 29].

Examples of generic clearance levels for selected radionuclides are provided in Ref. [8] derived for airborne releases, for liquid releases and for moderate quantities of solid waste. In general practice, these levels will usually differ depending on specific site authorizations.

As a rule, local authorities in each country establish clearance levels depending on location and capacity of facilities. In Russia each facility has a temporary license for a few years with the indication of clearance levels for every radionuclide. In Belgium discharge of liquid releases to drain below 1/100 ALI public/L is allowed without dilution provided ALARA can be demonstrated.

For quality certification of waste to be released, it is necessary to have an appropriate system for measurement of very low activity in samples of waste. Some commercial measuring systems have recently been developed for measuring the radionuclide content in medical and biological waste. It has been demonstrated that even low energy γ's such as ^{125}I bremsstrahlung emitted from packages of radioactive waste containing β emitters, or even low energy β's such as ^{35}S can be measured in plastic waste containers. Isotope characterization by spectrometry allows verification both qualitatively and quantitatively of the presence of particular radionuclides in a waste container. If a selective collection of isotopes has been made the amount can be measured far below clearance levels in low density waste forms. It is however not possible to detect tritium in waste containers. Procedures and quality control should be sufficient to comply with the usually very high clearance levels for tritium.

The quantitative measurement of initial activity can also result in an optimized choice of the decay period. The decay period of collected waste is generally defined by the rule: "10 half-lives of the longest lived radionuclide present". Measurements can confirm that this is sufficient to comply with clearance levels. The final clearance measurement should confirm that the residual activity does not exceed release criteria. Attention should be given to long living impurities in short living isotopes such as ^{114m}In (T½ 49 d) in ^{111}In (T½ 2.7 d).

Generic clearance without authorization, i.e. exemption [30, 31] could be very useful for small users of radionuclides who are normally producing wastes which are bulky but have a very low level of radioactivity. Most hospital facilities will have to apply clearance levels authorized by authorities on a case by case basis, taking into account local conditions and particular scenarios.

A quality assurance programme of radioactive waste flow, including separation and segregation of waste dependent of half-life of radioisotopes involved, combined with sensitive activity measurement, allows for waste management to be organized in such a way that clearance levels for waste as non-radioactive can be reached. Risk assessment of potential maximum releases of radionuclides should be prepared to convince the regulatory authority, as well as improve public confidence, that the discharges are environmentally sound.

9. QUALITY ASSURANCE AND CONTROL APPLIED TO BIOMEDICAL RADIOACTIVE WASTE

9.1. OBJECTIVES OF QUALITY ASSURANCE AND QUALITY CONTROL

The objective of quality assurance and quality control is to provide a systematic, well managed approach to ensure that all waste management activities are conducted in a consistent manner which meets regulatory requirements and ensures the safety of workers, patients, members of the public and protection of the environment. The extent of biomedical radioactive waste management quality control procedures will vary, depending upon the need to demonstrate to all relevant regulatory agencies that requirements are being met in full.

Quality assurance includes all of the planned and systematic actions, measures and procedures which should provide adequate confidence that items, processes or services will satisfy identified quality objectives. Quality control is the establishment of practices and procedures to confirm that these objectives are consistently achieved. Quality objectives may be defined as process requirements or standards. The effective implementation of a quality control and quality assurance programme will aid the healthcare facility operator in demonstrating compliance with the requirements of the regulatory organizations. Such a programme will ensure that wastes will be suitable for further management or disposal.

Information on the general requirements for designing a quality assurance programme can be found in ISO 9000 [32] or other relevant national and international standards [33]. It is recommended that Member States prepare their own standards for biomedical radioactive waste management based on the principles contained in these documents, having due consideration of all relevant regulations.

9.2. QUALITY ASSURANCE

9.2.1. General principles

Quality assurance is an essential aspect for the good management of biomedical radioactive waste. A quality assurance programme should provide the necessary controls over activities which affect the quality of structures, systems and components.

Quality assurance means all those planned and systematic actions necessary to provide adequate confidence that the objectives of waste management are being met. Internationally accepted requirements for quality assurance are given by the International Organization for Standardization in ISO 9000 [32]. Quality assurance programmes relevant to on-site medical radioactive waste management or a centralized waste management operation include:

— Handling, segregation, characterization, treatment, conditioning (if required), packaging storage, transportation and disposal;

— Record keeping;

— Training;

— Risk assessment.

— Audit.

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

Quality assurance programmes aim to ensure confidence that all operations are optimally managed, waste disposals and discharges are within authorized limits and that packages of waste are produce in conformity with the specifications required for storage and/or disposal.

A quality assurance programme is usually developed as part of a license application by the operator and is reviewed and approved by the regulatory agency. The programme should define and describe the organization, responsibilities, relevant quality assurance steps and organizational interfaces involved in management of biomedical radioactive wastes. A system for document control and records should provide evidence that the required quality has been achieved. Guidance on the development and implementation of a quality assurance programme for radioactive waste packages may be found in [34].

The guidance on quality assurance for biomedical radioactive waste is required by both the competent national authorities as well as by the individuals and organizations directly involved in managing the waste. However, the basic responsibility for achieving quality in performing a particular task rests with those assigned to that task, not with those seeking to ensure by means of regulation that it has been achieved.

The quality assurance programme adopted to satisfy all relevant regulatory requirements should be reviewed at appropriate intervals to ensure its continuing suitability and effectiveness. The organizations responsible for licensing of the waste producing establishment should review the development, implementation, maintenance and results of audits of the quality assurance programme at appropriate intervals to ensure continuing compliance with regulatory requirements.

9.2.2. Regulatory requirements

Compliance with regulatory requirements leads to quality assurance arrangements. A comprehensive series of quality control operations are often developed by the healthcare facility to define and describe the overall management and the interface arrangements with the various groups or organizations involved in handling, treatment, storage and disposal of medical radioactive waste. The overall quality assurance programme is usually developed as part of an application for license and is reviewed and approved by the relevant regulatory organization.

Those government regulatory organizations which have responsibility for defining the objectives of waste management quality control and quality assurance programmes should be identified and consulted, bearing in mind that several agencies may be involved. Within the framework established in individual countries for ensuring health and safety of the public, or

the regulations established for the operation of licensed establishments producing radioactive medical wastes, there must be provision for the effective implementation of quality control and quality assurance.

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Those government regulatory organizations which have responsibility for the outcome of waste management quality control and quality assurance programmes should be identified and consulted, bearing in mind that several agencies may be involved. Within the framework established in individual countries for ensuring health and safety of the public, or the regulations established for the operation of licensed establishments producing radioactive medical wastes, there must be provision for the effective implementation of quality control and quality assurance.

9.2.3. Training of personnel

Training of personnel is an integral part of the quality assurance arrangements. The procedures required for all operations involving the management of biomedical radioactive wastes at both the user=s premises or at a centralized facility will only be effectively implemented and maintained when supported by appropriate and timely training of personnel. The healthcare 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.

A training programme is recommended to initiate new staff and to periodically update existing staff. Training should usefully include fundamental and practical aspects of health care, safety and radiation protection, regulatory requirements, waste characteristics and details of quality control steps and operational procedures relevant to their role in the management of biomedical radioactive wastes. It is important to emphasize any site specific quality control procedures and requirements for documentation of such activities as may be necessary for the facility to demonstrate compliance with license conditions to the regulatory organizations.

The employer is advised to keep records of all training and retraining provided whenever procedures are revised. Refresher training should be provided 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. It is important that training is aimed at the level of knowledge and understanding of the individual as part of the overall management of the quality control system.

9.2.4. Risk assessment

Risk assessment is an essential component of a radioactive waste management programme for biomedical radioactive wastes. In many instances, the biological hazard of

these wastes greatly outweighs the radiological hazard. An integrated approach to risk assessment should be carried out with due regard to all relevant regulations and safety guidelines appropriate to the potential hazards that may exist at each stage of the waste management operation. The risk assessment should cover all of the operations and inherent hazards associated with every aspect of the management of radioactive waste at the user's premises. Risk assessments should also be required for "off-site" waste management practices, including the transport operation and the waste management programme operated by a centralized waste facility. These would be the responsibility of the operator of the services provided outside of the user's premises.

The introduction of quality control procedures aimed at mitigating the level of risk in the waste management programme is ideally achieved through the effective use of risk assessment. Where risks are identified, control procedures need to be drafted and implemented such as effective training of personnel and an immunization programme of employees considered to be at risk. When changes are required to operational procedures, competent persons are required to review the risk assessment (the safety manager/control of infection officer) to ensure that the potential risks have not increased as a result of the changes introduced. It is recommended that records of all accidents and incidents (including "near miss" events) are kept and are periodically reviewed in consultation with the risk assessment and operational procedures. To minimise risks prior to accidents/incidents, the quality assurance arrangements should include the assessment of health and safety performance through quality control inspections of facilities and processes. Such action can be used to verify the accuracy of the risk assessment and the satisfactory performance of operational procedures in compliance with the quality control programme.

9.2.5. 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 programme requirements, and other applicable documents.

The implementation and effectiveness of the quality assurance programme 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 should:

(1) verify that the programme and plans address the applicable requirements;

(2) verify that the programme and plan(s) requirements are adequately addressed in operating procedures, and

(3) verify that implementation of all quality control steps are adequate.

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 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.

Product auditing usually involves the direct examination of the product, e.g. waste form, the waste container or the waste package. It should be performed when the auditing organization possesses the testing and monitoring technology or expertise and the waste processor does not. Product auditing should also be performed when the waste processor samples, or examines his product on an ongoing or statistical basis.

It is clear that quality assurance programmes and audits will be different when biomedical radioactive wastes are managed on-site rather than at a centralized facility. A more complex system may be associated with a centralized facility, especially when the facility does not deal exclusively with radioactive wastes arising in the medical sector. Nonetheless, it is essential that appropriate quality assurance is applied to on-site management of biomedical radioactive waste, where maintaining standards may be more difficult because of the variety of activities undertaken and the limited resources that are likely to be available.

An example of the audit data that may be required and how to collect it in order to make the assessment is contained in the Annex.

9.3. QUALITY CONTROL

9.3.1. General principles

Quality control involves the operational techniques and activities aimed at monitoring and recording all of the essential requirements. It should be based, as far is practicable, on the control of each element of the waste management process and includes, but is not limited to, the following:

— the identification of all factors which determine the characteristics of the waste, including radionuclide content, physical/chemical/biological hazards associated with the waste and any further properties, as appropriate;

— measurements to verify that the characteristics of wastes generated are within expected limits;

— the identification of equipment and process control parameters which ensure that the waste characteristics remain within pre-determined limits;

— the identification of the means of measurement or quantification parameters necessary to achieve the appropriate standard of accuracy and reliability in relation to the waste being generated;

— measurements to verify periodically the acceptability of the experimental/working parameters and to modify them as necessary to ensure that the waste being generated is minimized and effectively managed;

— final check, prior to transfer, of the identity and conformity of the radioactive waste packages, carried out by appropriate methods;

— documentation and the need for it should be periodically reviewed as to accuracy, relevance and compliance with all current practices, having due regard to relevant regulatory requirements;

— appropriate documentation of checks on quality control measures and procedures;

Biological, chemical and physical, as well as radiological hazards, must be considered. Detailed operational quality control procedures are required for all aspects of the waste management programme. Procedures should cover both normal and abnormal operations.

9.3.2. Record keeping

The preparation and maintenance of a comprehensive system for record keeping is an essential component of both the waste management system and the quality control programme. The need for recording specific information regarding the waste generation, and its subsequent handling, treatment, storage and disposal, as well as the labeling of individual waste packages has been described previously (Section 4.3). In many instances, local regulations govern the records that are required to be kept. Records should be clear, legible, permanent and maintained up to date at all times, such that they are readily available for inspection. 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 agencies may be required.

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 package. One way this can be achieved is by use of a bar coding system which can be read into a computer database. The quality control system should detail the period of retention of records. 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 the 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.

10. CONCLUSIONS AND RECOMMENDATIONS

This report provides practical guidance primarily to developing Member States but is applicable to all States who manage biomedical radioactive waste arising in hospitals, clinics, medical laboratories, and medical institutions. Conclusions and recommendations derived from the document are listed below.

— Characteristics of radionuclides used in medicine are extremely diverse. Sources must be fully characterized in radiological, chemical, biological and physical terms and within their diagnostic, therapeutic, and research applications as a precursor to effective biomedical waste management.

— Adequate management of waste, its prevention and minimization should be a primary focus of the waste management programme.

— In addition to radiological health protection measures for biomedical radioactive waste, other non-radiological hazards must be considered such as, physical (sharps) infectious, and chemical hazards. Universal Precautions must be practiced in an integrated way.

— Selective collection and segregation of waste at source is pre-requisite to an effective waste management programme.

— Clearance levels achieved through dilution to reduce specific activity levels may be considered by some Member States. It is essential that the environmental impact is assessed before such practices are introduced.

— Returning radionuclides used in specific medical procedures and the resulting waste to the manufacturer or supplier/vendor is an acceptable practice that should be encouraged depending on cost effectiveness.

— Most radionuclides used in medicine and especially those used for diagnostic purposes, have relatively short half lives (i.e. typically less than 10 days but may be up to 100 days). Therefore, full use of on-site decay methods should be utilized so that waste can be disposed of at the clearance levels authorized by the relevant regulatory agency based on risk assessment.

— It is preferable to reduce radioactive material to insignificant levels by decay prior to on-site or off-site treatment as biologically contaminated waste following the performance of appropriate measurements. On-site treatment is preferable if practical, appropriate and cost effective.

— Effective radioactive waste management strategies should include all steps from waste collection to final disposal with on-site or centralized treatment considered or a combined strategy.

— The operator should implement the process options for biomedical radioactive waste management that are the most cost effective to procure and operate, and which satisfy all local and national requirements.

— The management of biomedical radioactive waste is not a static process. Annual reviews of on-site and centralized programmes should be conducted because:

  (1) New uses and clinical procedures may alter the characteristics of biomedical radioactive waste.

  (2) Changes in regulations in Member States may require revisions in management procedures and strategies.

  (3) Changes in volumes and composition of biomedical radioactive waste may result in new pricing structures, or the final disposal route may increase their pricing structure making use of that disposal route no longer viable.

— Where numerous waste producers have developed independent waste management procedures on an ad hoc basis, an overall review of radionuclide usage, waste arisings and available disposal routes should be carried out in order to develop a cost-effective biomedical radioactive waste management strategy in full compliance with regulatory requirements.

— Quality assurance and control should be implemented for all steps of the waste management strategy — handling, packaging, measurement, training, auditing, risk assessment, relevant regulatory requirements and record keeping.

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GLOSSARY

Angioplasty — a term used to describe a medical procedure usually carried out in the X ray department which involves reconstruction of a diseased or injured blood vessel.

Ablation — a term used medically to describe total removal of a body organ or tissue. In respect of ablation therapy, this involves removal by radiation exposure rather than a surgical procedure.

Anatomical marking — a pen point marker usually a sealed radioactive source, used to anotate positioning a patient.

Brachytherapy — brachytherapy is where the radioactive source being used to treat the cancer is usually in contact with the patient, either by being introduced into a natural body cavity or by being directly implanted into tumour-bearing tissue.

Carcinoma — a cancer.

Catheterization — to insert a tube into a body cavity, usually for the purposes of introducing or removing fluid.

Chemotherapy — treatment of disease by chemical substances which act on malignant tissue.

Deactivation — to remove capability of reacting chemically.

Desinfection — to cleanse from infection by destroying germs.

DNA sequencing — a laboratory technique to ascertain the order of base pairs in deoxyribonucleic acid (DNA) which carries the genetic code in cells.

Healthcare — Provision of care for human health.

HIV — human immunodeficiency virus.

Gamma knife surgery — a bloodless procedure where high energy gamma radiation is used to perform surgery.

In vitro — in the laboratory, where radionuclides are used as tracers in laboratory tests.

In vivo — in the body. When applied to radionuclides, it involves the patient being injected with, or swallowing the radionuclide.

Infection — spread of disease.

Isotonic — having the same osmotic pressure.

Malignant — in reference to a tumour, the tumour is invading normal tissue, is cancerous, and may recur after removal.

Metastases — the spread of a primary cancer from one organ or part of the body to another to produce secondary cancers, or metastases.

Oncology — the science of new growth, i.e. cancers.

Pathological — diseased.

Putrescible — a tendency to rot/decompose.

Palliative — used to alleviate pain without curing the problem.

Stenosis — a medical term used to describe the abnormal narrowing of a blood vessel in the body or of a lumen in a tubular organ.

Sterilization — the process of rendering free from contamination by microorganisms by treatment, usually with heat or chemicals.

Teletherapy — the treatment of disease from a distance. When applied to cancer treatments, this involves either external beam therapy with high energy X rays or exposure to the gamma radiation from a high energy sealed source.

Thyrotoxicosis — a medical condition whereby the thyroid gland produces an excess of thyroxine hormone which controls the rate of metabolic processes within the body, making the person over-active.

Universal precausions — a fixed set of precautions which, when universally applied, will avoid spread of infection.

Annex

AUDITS

Audit of waste producers facility to assess radioactive waste management requirements.

(1) How many individual medical departments/laboratories/research units within the premise are using radionuclides?

(2) Is there centralized management of purchase of radionuclides? If not, how is it managed.

(3) Obtain data to construct a list of all radionuclide usage on the premise, and actual frequency and activity at the time of purchase of individual radionuclides. Ascertain whether centralized purchase/aliquoting/distribution of radionuclides could reduce costs and minimize disposal of surplus stocks that have been purchased.

(4) Does the premise operate under a license/authorization and/or to exemption order limits? Obtain copy and verify authorized disposal routes and limits.

(5) Is there a potential disposal route not currently licensed/authorized that could be beneficial for future disposal of radioactive waste? If so, has an application to add this route been authorized?

(6) What is the maximum period that waste is authorized for accumulation on the premises? Would it be environmentally beneficial for the period to be extended?

(7) Who is organizationally responsible for management of the radioactive storage facility and the associated record keeping?

(8) Name of any on-site Radiation Protection Supervisor(s) and/or Radiation Protection Adviser with contact telephone number.

(9) Name of contact on site who has responsibility for consignment of radioactive waste disposals off-site.

(10) What frequency of collection of waste from the premises is currently in force?

(11) Describe the current waste disposal arrangements both at the point of generation in individual laboratories until final disposal from the premises. Is technical assistance/training required to help improve waste minimization practices?

(12) How is the radioactive waste quantified at source? Is standard methodology adopted throughout the premises? (Request copy of any quality documentation/protocols which relate to radioactive waste arisings).

(13) What level of confidence ($\pm$%) can be put on the declared radionuclide content of each of the packages of waste being produced? How is this figure arrived at?

(14) Is there any waste for which producers are unhappy about their current method of quantification and wish to receive technical support to improve?

(15) Describe the nature and quantity of the overall radioactive waste arisings, both in terms of character of the waste and volumes (not activity in MBq)

Solids

Sharps

Putrescibles

Scintillant

Sealed sources

Animal house litter

(16) Number of bags/bins of each type of waste produced and frequency of production. Average weight of a bag of waste?

Do they comply with the requirement not overfill the bag so that it can be tied at the neck for handling?

Do they comply with the requirement not to overfill sharps containers?

(17) a selected route/in a defined period? What confidence exists that these are complied with?

(18) What mechanism exists for disposals of unpredicted waste arisings, e.g. from clean up of a spill? How would this be quantified and the disposal controlled?

(19) Does the waste produced on the premises which requires incineration contain heavy duty glass bottles, e.g. carbon-14 Bactec bottles?

a. What is the total quantity of glassware in an average consignment of waste for incineration?

(20) Where additional regulations are applicable to the disposals of waste, e.g. the waste contains prescription only medical radiopharmaceuticals or low flash point organic scintillants, are these regulations being complied with in addition to radioactive regulatory control?

(21) Do current segregation and packaging practices optimize the use of potential disposal routes?

(22) Where required can it clearly be demonstrated that existing practices are in compliance with a quantity plan for disposal of waste to an identified facility, i.e. a repository for storage.

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