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Radiological protection — Measurement for the clearance of waste contaminated with radioisotopes for medical application —

Part 2: Management of solid radioactive waste in nuclear medicine facilities

Radioprotection — Mesurage pour la libération des déchets contaminés par des radioisotopes lors des applications médicales —

Partie 2: Gestion des déchets radioactifs solides dans les installations de médecine nucléaire

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

A list of all the parts in the ISO 19461 series can be found on the ISO website.

Introduction

Nuclear medicine is the branch of medicine which uses in vivo radioactive tracers, also called radiopharmaceuticals, to evaluate molecular, metabolic, physiologic or pathologic properties in human beings and animals for diagnosis, monitoring and therapeutic purposes. The use of radionuclides in medicine is a well-established practice. Their favourable physical properties allow a broad use of radionuclides in vivo, in modern medicine. As a result, a wide range of radioactive waste is produced. Most of it is considered biomedical radioactive waste. The amount and types of wastes varies depending on the scale of the nuclear medical facility, the medical applications, and the involved radionuclides.

Radioactive waste generated in nuclear medicine facilities does not present a significant long term waste management problem when compared to wastes generated from nuclear fuel cycle operations, for instance. The most important characteristics of biomedical radioactive waste produced in nuclear medicine are its short half-life and low radiotoxicity. It generally contains low-energy photon emitters (<511 keV), but also alpha and beta (β^+ and β^-) emitters. It is usually of low total and specific activity. Nevertheless, the volume of radioactive waste produced can be significant, and other associated hazards may be present, such as biological and physical risks.

The radioactive waste produced is mainly in solid or liquid form. The liquid form is associated with patient urine, since it is the main elimination mechanism of radiopharmaceuticals. Liquid waste can also be associated with the washing water of potentially contaminated material or residues of syringes, vials, etc. This liquid waste possesses a particular management problem that falls outside the scope of this document. Liquids in small quantities contained in vials and syringes are generally managed as solid waste and their management is part of this document.

When planning for the handling of radionuclides in nuclear medicine facilities, it is important to design an effective program 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 preparation for discharge or disposal. The goal is to minimize the hazards posed by radioactive waste, including the associated biological and physical hazards.

Radiological protection — Measurement for the clearance of waste contaminated with radioisotopes for medical application —

Part 2: Management of solid radioactive waste in nuclear medicine facilities

1 Scope

This document addresses aspects of management of solid biomedical radioactive waste from its generation in nuclear medicine facilities to final clearance and disposal, as well as the manner to establish an effective program for biomedical radioactive waste management.

Liquid and gaseous wastes are excluded from the scope of the document, but solid waste includes spent and surplus solutions of radionuclides contained in vials, tubes or syringes. Therefore, this document should be useful for any nuclear medicine facilities dealing with in vivo medical applications of radionuclides and consequently with the waste associated with such applications.

This document provides a list of the main radionuclides used in nuclear medicine facilities and their main physical characteristics, as well as the guidance to write a radioactive waste management program for their sorting, collection, packaging and labelling, radioactivity surveys and decay storage, clearance levels, and transportation, if necessary, until their ultimate disposal or discharge. This document may also be useful as guidance for regulatory bodies.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 19461-1, *Radiological protection — Measurement for the clearance of waste contaminated with radioisotopes for medical application — Part 1: Measurement of radioactivity*

ISO 23907-1, *Sharps injury protection — Requirements and test methods — Part 1: Single-use sharps containers*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
activity
A
quotient of $-dN/dt$, where dN is the change in the number of radioactive nuclei, at a particular energy state and at a given time, due to spontaneous nuclear transformations in the time of interval dt

Note 1 to entry: The special name for the unit of activity in the International Systems of Units is Becquerel (Bq), where 1 Bq = 1 s^{-1}.

[SOURCE: ISO 12749-1:2020, 3.1.2]

3.2
biological waste
material that possibly contains or has been contaminated by a biological agent that has the capacity to produce deleterious effects on humans or animals

Note 1 to entry: Biological waste includes, but is not limited to, Petri dishes, surgical wraps, culture tubes, syringes, needles, blood vials, absorbent material, personal protective equipment and pipette tips.

3.3
biomedical radioactive waste
waste possibly containing both radioactive and biological waste

3.4
calibration
set of operations that establish, under specific conditions, the relationship between values of a quantity and the corresponding values traceable to primary standards

[SOURCE: ISO 17665-1:2006, 3.5, modified — "indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material" was deleted.]

3.5
clearance level
value established by the competent authority, expressed in terms of *activity* (3.1), activity concentration or surface contamination (fixed and non-fixed) at or below which radioactive material or radioactive objects within authorized practice may be removed from any further regulatory control by the regulatory body

[SOURCE: ISO 19461-1:2018, 3.5]

3.6
decay
<radioactive> spontaneous nuclear transformation of one nuclide into a different nuclide or into a different energy state of the same nuclide

[SOURCE: ISO 12749-1:2020, 3.1.10]

3.7
discharge
planned and controlled release of radioactive material to the environment

[SOURCE: Adapted from IAEA: Radioactive Waste Management Glossary: 2003 Edition, Vienna]

3.8
disposal
emplacement of waste in an appropriate facility

[SOURCE: Adapted from IAEA: Radioactive Waste Management Glossary: 2003 Edition - Vienna]

3.9
elution
process of extracting one material from another by washing with a solvent

Note 1 to entry: Process used for the production of certain radionuclides in nuclear medicine facilities, such as molybdenum-99/technetium-99m, rubidium-81/krypton-81m and germanium-68/gallium-68 generators.

3.10
fermentation
metabolic process that consumes sugar in the absence of oxygen. The products are organic acids, gases, or alcohol usually associated with enzymatic digestion by yeast and bacteria

3.11
fermentable waste
waste which ferments if not stored in an appropriate way (freezing, refrigeration)

3.12
half-life
$T_{1/2}$
time taken for the *activity* (3.1) of an amount of radionuclide to become half its initial value

Note 1 to entry: $T_{1/2} = \ln 2/\lambda$, where λ is the *decay constant* time required for the activity to decrease to half its value by a single radioactive decay process.

[SOURCE: ISO 12749-1:2020, 3.1.9]

3.13
ionizing radiation
radiation capable of displacing electrons from atoms or molecules, thereby producing ions

Note 1 to entry: Ionizing radiation includes alpha radiation, beta radiation, neutron radiation, gamma or X-ray photons, and cosmic rays.

[SOURCE: ISO 12749-1:2020, 3.1.4]

3.14
nuclear medicine
field of medicine in which *unsealed radioactive sources* (3.27), namely radiopharmaceuticals, are used for diagnosis or therapy

Note 1 to entry: The techniques in this field can be broadly divided into two categories: in vivo (nuclear medicine facilities) and in vitro applications (biological laboratory).

[SOURCE: ISO 12749-6:2020, 3.1.1, modified — Note 1 to entry was added.]

3.15
radiation
emission or transmission of energy in the form of waves or particles through space or through a material medium

[SOURCE: ISO 12749-1:2020, 3.1.3, modified — Note 1 to entry was deleted.]

3.16
radiation source
apparatus, substance or installation, that may cause radiation exposure, by emitting *ionizing radiation* (3.13)

[SOURCE: ISO 12749-1:2020, 3.1.5, modified — "or releasing radioactive substances or materials" was deleted.]

3.17
shielding
radiation shield
materiel interposed between a source of radiation and persons, equipment or other objects, in order to reduce the radiation

[SOURCE: ISO 12749-1:2020, 3.1.7]

3.18
radioactivity
stochastic process whereby nuclei undergo spontaneous disintegration, usually accompanied by the emission of subatomic particles, or photons

[SOURCE: ISO 12749-1:2020, 3.1.1]

3.19
radioactive waste
material for which no further use is foreseen that contains or is contaminated with radionuclides at *activity* (3.1) greater than *clearance levels* (3.5) as established by regulatory body

[SOURCE: ISO 12749-1:2020, 3.5.1, modified — Note 1 to entry was deleted.]

3.20
radioactive waste management
all administrative and operational activities involved in the handling, conditioning, transport, radioactive material storage, and disposal of *radioactive waste* (3.19)

[SOURCE: ISO 12749-1:2020, 3.5.7, modified — "pre-treatment and treatment" were deleted from the definition.]

3.21
radioisotope
unstable isotope of an element that decays or disintegrates spontaneously, thereby emitting radiation

[SOURCE: ISO 19461-1:2018, 3.9, modified — Note 1 to entry was deleted.]

3.22
radionuclide
unstable isotope of an element that decays or converts spontaneously into another isotope or different energy state, emitting radiation

[SOURCE: ISO 16640:2021, 3.34]

3.23
radiopharmaceutical
radioactive drug used for diagnostic or therapeutic purposes

Note 1 to entry: The radiopharmaceutical is a radiotracer approved by regulatory authorities for routine human use.

Note 2 to entry: The radiopharmaceutical has two components: a radioactive part (radionuclide) that defines the physical parameters such as physical half-life and type of radiation for the medical procedure, and non-radioactive part (tracer, chemical and /or biological part) that defines the biological parameters such as biological half-life and specificity.

[SOURCE: ISO 12749-6: 2020, 3.4.3, modified — Note 1 to entry was added.]

3.24
radiopharmaceutical kit
preparation to be reconstructed or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration

[SOURCE: ISO 11616: 2017, 3.1.29, modified — Note 1 to entry was deleted.]

3.25
sealed radioactive source
radioactive material sealed in a capsule or associated with a material to which it is closely bonded, this capsule or bonding material being strong enough to maintain tightness of the sealed source under the conditions of use and wear for which it was designed

[SOURCE: ISO 12749-2:2013, 6.3]

3.26
sharps waste
form of waste composed of used "sharps", which includes any device or object used to puncture or lacerate the skin. Sharps waste is classified as hazardous waste

Note 1 to entry: Common medical materials treated as sharps waste are needles, syringes, lancets, scalpels, blades, and contaminated glass.

3.27
unsealed radioactive source
radioactive source which is not sealed into a capsule

Note 1 to entry: In nuclear medicine, unsealed radioactive sources allow the fractionation of radioactivity for the preparation of radiopharmaceuticals, which may also be responsible for a dispersion of radioactivity.

[SOURCE: ISO 5576:1997, 2.123, modified — The word "radioactive" was added in the term and the Note 1 to entry added.]

3.28
waste
any residue of a production operation, transformation, or use, any substance, material, product that its holder intends for disposal

[SOURCE: ISO 22716:2007, 2.36]

4 Fundamentals

4.1 Characteristics of radionuclides used in nuclear medicine facilities

4.1.1 General

The principle of in vivo nuclear medicine is to administer a radiopharmaceutical, usually injected into the bloodstream, inhaled or swallowed, to target a physiological function for diagnostic, monitoring or therapeutic purposes. These radiopharmaceuticals are unsealed radioactive sources. They are either ready-to-use preparations or derived from radiopharmaceutical kits. Some radionuclides are produced in nuclear medicine facilities using a generator such as molybdenum-99/technetium-99m generators. Sealed sources are also used for anatomical marking, quality control and calibration of medical devices. The list of the main radionuclides used in nuclear medicine facilities and their medical applications are given in Tables 1, 2 and 3.

4.1.2 Diagnosis and patient monitoring

The main application of in vivo nuclear medicine is diagnostic imaging. The principle is to administer a radiopharmaceutical, which consists of a radionuclide linked to a chemical compound. The chemical

compound allows a specific physiological process to be scrutinized. The radionuclide allows the emission of photons from inside the body, whose signal is collected to create an image or the measurement on biological samples. The uptake of the radiopharmaceutical depends on the targeted physiological function or tissue metabolism or organ blood flow. As gamma rays are penetrating, they can be detected by an imaging device adapted to this type of radiation. The camera builds an image from the photon emission points. Depending on the nature of the radionuclide (gamma emitter or positron emitter), there are two types of imaging device: Gamma camera based on the detection of a single photon from gamma emitters and Positron Emission Tomography scanner (PET-scanner) based on the coincidence detection of 511 keV photons from positron emitters.

The main photon emitter used is ^{99m}Tc. The usual range of administered activity is 40 MBq to 800 MBq, with lower activity administered for paediatric patients. Other common photon emitters used include ^{67}Ga, ^{111}In, ^{123}I and ^{201}Tl. These radionuclides are usually administered at activity levels in the range of 40 MBq to 400 MBq.

Table 1 — Main radionuclides used as unsealed sources in the compounding of radiopharmaceuticals

Radionuclide	Half-life	Principal application
^{11}C	20,3 min	PET imaging
^{18}F	1,8 h	PET imaging
^{51}Cr	27,7 d	Measurement on biological samples
^{59}Fe	44,5 d	Measurement on biological samples
^{67}Ga	3,26 d	Single-photon imaging
^{68}Ga	1,13 h	PET imaging
^{81m}Kr	13 s	Single-photon imaging
^{82}Rb	75 s	PET imaging
^{89}Sr	50,5 d	Therapy
^{90}Y	2,7 d	Therapy
^{99m}Tc	6,0 h	Single-photon imaging
^{111}In	2,8 d	Single-photon imaging
^{123}I	13,2 h	Single-photon imaging
^{125}I	59,4 d	Measurement on biological samples
^{131}I	8,0 d	Therapy Single-photon imaging
^{153}Sm	47 h	Therapy
^{177}Lu	6,64 d	Therapy
^{201}Tl	3,0 d	Single-photon imaging
^{223}Ra	11,4 d	Therapy
^{225}Ac	10,0 d	Therapy

Some radionuclides can be directly produced in nuclear medicine facilities based on radionuclide generators. The most well-known is the molybdenum-99/technetium-99m generator, where ^{99}Mo is absorbed on alumina in a lead-shielded column providing a daily elution of several hundred MBq of sodium pertechnetate ^{99m}Tc solution. This solution is used to prepare ^{99m}Tc labelled radiopharmaceutical from a radiopharmaceutical kit.

Some radionuclides are also used to label the components of human blood. After the blood is collected, it is radiolabelled and reinjected into the patient. Examples of the radionuclides used include ^{99m}Tc, ^{111}In, ^{51}Cr, ^{59}Fe and ^{125}I. The activity that is re-injected is usually in the range of a few MBq to a maximum of 200 MBq. 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 or ^{99m}Tc aerosol inhalation up to 80 MBq inhalation activity.

Table 2 — Main radionuclides used as unsealed sources generators

Parent nuclide	Half-life	Daughter nuclide
^{68}Ge	270,9 d	^{68}Ga
^{81}Rb	4,57 h	^{81m}Kr
^{82}Sr	25,34 d	^{82}Rb
^{99}Mo	66 h	^{99m}Tc

The main positron emitter used is fluorine-18, combined with various chemical compound in the form of ready-to-use preparations for one or more patients, such as 2-deoxy-2-(^{18}F)fluoro-D-glucose (^{18}FDG). There is also the development of the use of gallium-68 and rubidium-82 from respectively germanium-68/gallium-68 and strontium-82/rubidium-82 generators.

The physical half-life of unsealed sources composing the radiopharmaceuticals ranges from a few seconds (^{81m}Kr) to a few days (^{201}Tl, ^{111}In, ^{67}Ga) (see Table 1), while that of sources contained in generators ranges from a few hours (^{81}Rb) to several months (^{68}Ge) (see Table 2).

4.1.3 Therapy

Many radionuclides are also used in vivo as unsealed sources for therapeutic applications. The activity is much higher than those used for diagnosis. Most of them are β^- emitters, associated or not to γ or β^+ emissions. The most commonly used is ^{131}I for the treatment of thyroid disease (thyrotoxicosis and ablation of the thyroid tissue or metastases for cancer treatment). Individual patient activities are typically in the range of 200 MBq to 5,5 GBq. This radionuclide is also used for other types of cancers (primary or metastasis) for treatment or palliative purposes, as well as other β^- emitters (^{90}Y, ^{177}Lu, ^{89}Sr, ^{153}Sm) and alpha emitters (^{223}Ra, ^{225}Ac).

Several radionuclides are used in the treatment of joint pain (^{90}Y, ^{89}Sr, ^{153}Sm) (see Table 1).

4.1.4 Sealed sources

Sealed radiation sources may also be used for technical reasons:

— for quality control of radionuclide calibrator (^{133}Ba, ^{57}Co, ^{137}Cs);

— for quality control of gamma camera (^{57}Co) or PET-scanner (^{68}Ge, ^{75}Se);

— for anatomical marking (^{57}Co).

Since these sealed sources may have small dimensions and low activity, special care should be taken to ensure that they are not lost in use. For practical reasons, these sources generally have a radioactive half-life of several months or even a few years (see Table 3).

Table 3 — Main radionuclides used as sealed sources in nuclear medicine facilities

Radionuclide	Radioactive half-life	Principal application
^{57}Co	271,7 d	Anatomical marking, quality control
^{68}Ge	270,9 d	Quality control and calibration
^{75}Se	119,8 years	Quality control
^{133}Ba	10,5 years	Quality control
^{137}Cs	30,08 years	Quality control

4.2 Classification and characteristics of solid radioactive waste

4.2.1 Introduction

The handling of unsealed radioactive sources, the preparation of radiopharmaceuticals, and their administration result in the production of radioactive waste. This waste may be associated with other risks that shall be taken into account. In addition, the presence of outdated generators and used sealed sources shall also be managed.

4.2.2 Associated non-radiological hazards

The handling of unsealed radioactive sources for medical purposes requires the use of sharp objects (syringes, needles, glass vials, etc.), which can be responsible for cutting and puncture injuries. These physical hazards are commonly referred to as sharps waste.

Waste generated in a health care facility is likely to be contaminated with human blood, other body fluids, or any potentially infectious material which necessitates considering them as biological waste.

Fermentable radioactive waste can also be produced from food waste of hospitalized patients treated by a radiopharmaceutical due to the presence of radioactivity in saliva and the storage of waste during several weeks for radioactive decay. This case is found in the treatment of thyroid cancer by ^{131}I.

In many instances, these potential additional hazards are greater than the radiological hazard. It shall be stressed that, after the appropriate decay storage period, the clearance level of radioactive waste is reached, while the other associated risks still exist (sharps waste) and could increase (e.g. biological/infectious hazard/fermentation).

4.2.3 Categories of radioactive waste

Due to the presence of sealed and unsealed sources, the different risks associated with radiological hazards, several waste circuits and management shall be identified corresponding to different waste categories[11]. It is recommended to identify different categories of waste with different management circuits. The waste categorization shall be in conformity with any existing national and local safety standards. An example of different categories of waste is defined below and is grouped in Table 4.

— **Category 1 (Cat 1)** Miscellaneous solid and semi-solid, dry or wet radioactive waste, without any other additional hazard coming from unsealed sources. This category corresponds to radioactive waste without any contact with biological material (e.g. filters used in equipment, etc.). This category can be grouped with category 2, based on maximum risk, i.e. biological risk. The advantage is to reduce the cost of dealing with the waste when they are not grouped together. The disadvantage is having to manage an additional category.

— **Category 2 (Cat 2)** Miscellaneous solid and semi-solid, dry or wet radioactive waste, with an additional biological/infectious hazard: gloves, compresses, cotton, furniture, some medical devices and materials which may have come into contact with patients, such as urinary protection and sanitary towels for patients hospitalized for treatment, etc.

— **Category 3 (Cat 3)** Miscellaneous radioactive sharps waste (e.g. needles, syringes, glass, vials, tubes, etc.), spent radioactive solutions, such as ^{99m}Tc elution, radiopharmaceutical preparation, and surplus solutions of radionuclides, or radiopharmaceuticals from diagnostic and therapeutic applications can be classified in this category. Some of these sources are liquid and are managed as such for certain national or local regulations. Otherwise, they can be managed as solid waste because they are confined and volumes are low (generally < 20 mL). These solutions are usually contained in glass or vials. Due to the fragility of the container they are considered and managed as sharps waste. Most of these wastes may also present an additional biological risk. It is possible to separate this category of sharps waste into 2 categories depending on whether there is an associated infectious risk or not. The disadvantage is to add a category with a risk of sorting error, but with the advantage of lower cost. In the rest of the document, only one category is considered, grouping together sharps waste with and without associated infectious risk.

— **Category 4 (Cat 4)** Food waste from patients administered with radionuclides for therapeutic purposes (e.g. ^{131}I from hospitalized patients treated for their thyroid cancer). This type of waste is considered as fermentable waste.

Table 4 — Example of the different categories of waste produced in nuclear medicine facilities

Type of radioactive waste	**Unsealed**				**Unsealed, sealed sources or generators, long half-life impurities**
Category of waste	Cat 1	Cat 2	Cat 3	Cat 4	Cat 5
Associated risk	None	Biological	Sharps and biological	Fermentable	None
Waste description	Radioactive waste without any other additional hazard	Dry or wet radioactive waste with an additional biological/ infection hazard	Radioactive sharps waste with a possible additional biological/ infection hazard	Contaminated food waste	Unsealed, sealed sources, generators or radionuclides with long half-life impurities
Examples	Filters	Gloves, compresses, cotton swabs	Vials, glass, needles with spent radioactive solutions	Food waste from hospitalized patients treated by ^{131}I for their thyroid cancer	Disused radioactive sources and radionuclide generators

— **Category 5 (Cat 5)** Disused radioactive sources and radionuclide generators. Disused sources may be sealed or unsealed. For unsealed sources, depending on the production method, long half-life impurities may be present, such as samarium-153 with impurities of europium-154 ($T_{1/2}$ = 8,6 years) for instance. In general, the radiopharmaceutical is used for a patient and the activity of waste is very limited. However, it is possible that the radiopharmaceutical is not administered. Then, it is recommended to put unsealed sources with associated long half-life impurities in category 5.

5 General recommendations

5.1 General scheme of radioactive waste management

Radioactive waste management can be separated into several steps, such as:

— segregation and collection of radioactive waste, taking other associated risks into account;

— packaging and labelling;

— radioactivity survey;

— storage;

— disposal and discharge according to the clearance level associated with the radioactivity survey;

— transportation.

5.2 Segregation and collection

5.2.1 General recommendations

The segregation and collection processes have to be in conformity with any existing national and local safety standards on radionuclide waste, but also on biological/infectious, fermentable, and sharps wastes.

The objective of waste segregation and collection is to minimize the volume, cost, complexity, and risks associated with subsequent waste management steps. One of the aims of the radioactive waste management program is to define the segregation and collection strategy. Packaging shall be properly secured, and ergonomic principles shall be used for the safety of hospital staff and medical waste disposal workers, in conformity with good medical practice.

As recommended in IAEA-TECDOC-1183[11], "the segregation at the point of origin is more efficient than performing segregation after mixing". Thus, segregation at the point of generation is an essential component of the waste management process. Increased segregation involves more waste bins, greater risks of sorting errors, and can lead to compromises. The highest risk should always be given priority.

The segregation is sometimes easy due to different area of production. For instance, the circuit of fermentable radioactive waste (Cat 4) and disused radioactive sources (Cat 5) are separated and can be easily identified. On the other hand, waste from Cat 2 and 3 are often produced in the same area during the same medical act.

5.2.2 Waste package and shielding

It is recommended to have a range of types and sizes of bins/containers for segregation of the different categories of solid radioactive wastes at the time and place of production adapted to the volume of waste produced in a given working area. Waste shall be collected in packaging appropriate to its category. Bins shall be shielded in accordance with the radiation emissions and their energy. Bins with foot operated lids are particularly recommended to avoid contamination of workers.

If the radioactive waste management program has defined several categories of waste, the associated bins shall be clearly labelled to identify the different risks, such as:

— radiation risk;

— radionuclides that can be collected;

— associated risk (sharps, biological/infectious, etc.).

5.2.3 Recommendations by waste category

When considering the proposals for the different waste categories in 4.2.3, it is possible to make different recommendations for waste segregation and collection. These recommendations are given as examples and should not replace national or local regulatory requirements.

Cat 1 This category of waste is actually quite rare. It is preferable to collect it as soon as it is collected separately from other waste produced and in a clearly identified manner.

Cat 2 This waste is voluminous and produced throughout the day at various locations in the nuclear medicine facility. It can be advantageous to sort this radioactive waste according to physical half-life in order to limit the number of bags/containers stored for decay and to facilitate their management. The shorter the half-life, the faster the bag/container can be disposed. This solution and the range of radioactive half-lives that can be grouped together depend on several local factors, such as:

— the number of radionuclides used and their respective half-life;

— the type of radiation emissions and their energy to sort radioactive waste according to the same adapted shielding.

— the working area where they are used;

— the volume produced for each radionuclide;

— how the different radionuclides are used in the course of the day (planning of medical examinations);

— the size of the storage area.

An example of grouping radionuclides according to their half-life is given:

— $T_{1/2}$ < 2 h, radionuclides generally used in PET imaging (positron emitters), since one day after the waste production and packaging, most of the time the clearance level is reached and the waste can be managed as a non-radioactive waste;

— 2 h < $T_{1/2}$ ≤ 1 d, such as ^{123}I and ^{99m}Tc;

— 1 d < $T_{1/2}$ ≤ 4 d, such as ^{67}Ga, ^{111}In, ^{201}Tl;

— $T_{1/2}$ > 4 d, such as ^{131}I.

It also may be useful to separate radionuclides as a function of radiation emissions. Waste management can be very different between photon, beta and alpha emitters used for radioactive survey and estimation of amount of radioactivity in waste. As alpha and beta emitters are used for radiotherapy applications, the number of patients that are treated per day is limited and the process is more secured than in diagnosis (radiation protection of patients). It is then easier to dedicate a packaging by radionuclide.

Cat 3 Like category 2 waste, this waste is produced throughout the day in accordance with the clinical activity of the nuclear medicine facility. They are often produced at the same time during the preparation of radiopharmaceuticals and patient care. It is best to sort them according to the same sorting rule as category 2 waste. When selecting containers for biological sharps, consider the type of ionizing radiation and the shape of the waste in the container.

Cat 4 Fermentable radioactive waste should follow a clearly identified segregation and collection process that is separate from other types of waste. This is easy to achieve because the production and circuit of this waste is very specific.

Cat 5 Disused radioactive sources, generators and radionuclides with long half-life impurities should follow a clearly identified segregation and collection process that is separate from other types of waste.

5.3 Packaging and labelling

5.3.1 General recommendations

As recommended in IAEA-TECDOC-1183[11], “appropriate packaging and correct use of such packaging are essential components of the waste management system for biomedical radioactive waste”. This packaging shall be placed in an appropriate shielded waste container adapted to the photon energy of radionuclides used to provide reliable radiation protection of staff and containment during waste collection. Other packaging considerations for waste to be stored include:

— ease of closure/sealing of the radioactive waste packages to prevent dispersion/leakage of contents[11];

— ability of the packaging to withstand typical storage and use, without deterioration;

— packaging volume in accordance with the filling speed of the packaging;

— suitability of shape and size of the filled packages to optimize use of the available storage arrangements[11].

Bags/containers should be closed and not over-filled to prevent any loss of integrity (e.g. 3/4 full)[11]. For optimized protection, it is better to close the bag in the morning before the day's work begins.

Each handling of bag/container shall be done with disposable gloves available. Bags/containers shall be effectively sealed before handling. Bags are to be handled with care to preserve their integrity, and only by the part dedicated to this purpose (carrying handle, etc.). They shall not be clasped against the body.

The use of plastic bags or single use polyethylene drum containers for medical radioactive waste containment have the advantage that damp wastes do not seep through them and contaminate the floor. The strength of the bag should be appropriate for the weight of the waste because of the risk of rupture with resultant loss/leakage of contents.

As recommended in IAEA-TECDOC-1183[11], and when available, "single use disposable plastic containers with lids should be used. These containers once lidded and sealed are especially useful as they are leak free, even if the container becomes inverted during handling. Additionally, theses containers have the advantage that they are suitable for incineration in furnaces designed for plastics." Furthermore, the shape of hermetically closed polyethylene containers makes them suitable for optimized close stacking for short-term storage prior to disposal.

When the bag/container is closed, it shall be labelled with a unique identification for a complete traceability of the waste. One way to do this is the use of a barcode system associated with a computer database. At a minimum, the labelling shall allow easy identification of the waste category, date of closure, radionuclides, activity, or dose rate at closure according to the radioactivity survey (see 5.4), clearance levels and disposal rules (see 5.6).

5.3.2 Specific recommendations for certain waste categories

When selecting packaging for biomedical radioactive wastes, it is necessary to consider the different types and properties of waste generated, and also the circuits of waste management. Choice of the types of materials and package style is necessary to minimize waste volume and should be in conformity with any existing national and local safety standards, as well as good medical practice for each risk associated to radioactive waste.

Cat 2 The best is to fill the packaging during no more than one day to prevent biological hazards. On the other hand, if there is a proven infectious risk from an identified patient, the bag should be closed as soon as possible. Regulations for biohazardous waste in some countries require hermetically sealed polyethylene drums or specific packaging to be used instead of plastic bags.

Cat 3 Special consideration shall be given to the management of contaminated sharp objects by applying ISO 23907-1.

Cat 4 The shape of hermetically closed polyethylene containers is well adapted for radioactive fermentable waste because they may retain offensive odours during storage prior to disposal of the waste.

5.4 Radioactivity survey

5.4.1 General recommendations

The estimation of the activity of the waste is important for handling and storing of the package, and to estimate the decay period before disposal. Precise rules shall be defined to estimate this activity to be able to respect the clearance for the release of radioactive waste.

Determining the amount of radioactivity in the waste shall be done in conformity with any existing national and local safety standards, but three strategies are possible. They shall be adapted to setting clearance levels for the discharge of radionuclides (see 5.6). The first one is the measurement of activity. A second possibility is to estimate the amount of radioactivity. The third is to measure the dose rate. Regardless of the method used, this estimate is complex and highly prone to error, which does not pose a major problem in the context of radionuclides with short half-lives, low levels of radioactivity and low radiotoxicity.

When this estimate is based on a measurement, it is necessary that the measuring device be calibrated and checked regularly, and that the measurement is made in a low background environment. The background shall be measured beforehand and subtracted from the final waste measurement. Measurements are made without any interfering shielding, such as metal containers holding bags/containers to be disposed.

5.4.2 Activity measurement

Apply ISO 19461-1.

It should be noted that activity measurement is generally difficult to achieve and subject to uncertainties. It requires several manipulations and can be time-consuming. This strategy necessitates the sorting of waste by radionuclide, which can quickly become very complicated in clinics when the number of radionuclides used in the same room increases. The unit of measurement for the level of radioactivity in the waste can be in Bq or in Bq/g.

5.4.3 Activity estimate

The activity of the waste can be estimated from its mode of generation by extrapolating the amount of radioactive material used, current clinical protocols and data on typical waste properties. The highest amount of radioactivity comes from spent radioactive solutions (e.g. ^{99m}Tc elution, radiopharmaceutical preparation and surplus solutions of radionuclides or radiopharmaceuticals from diagnostic and therapeutic applications). Most of the time, the initial activity of these solutions is well known, as is the activity sampled over time. Most radiopharmaceutical management software is able to calculate the activity remaining in vials. In such a context, this survey strategy of radioactivity estimation can be used, but requires careful implementation, extensive staff training, and regular quality assurance of the waste management system.

This strategy should be used in the cases of pure β^- or α emitters or in the presence of long half-life impurities with these types of emissions, because the measurement and detection of pure β^- or α emitters is generally complicated.

5.4.4 Dose rate measurement

Since most radionuclides used in nuclear medicine facilities are photon emitters with energies between 100 keV to 511 keV, the simplest and quickest strategy is to perform a dose rate measurement. It shall be done with an appropriate gamma dose rate meter, at a specified distance from the bag/container. To reduce the possible effect of a non-uniform distribution of radioactivity within the bag/container, it is possible to position the detector at 1 m or at a specific longer distance. Another solution is to perform several dose rate measurements at contact all around the bag/container and to retain the maximum value measured. Count rate (cps) measurements can be used as a substitute for dose rate measurements.

This solution cannot be used for pure β^- or α emitters, nor for radionuclides whose long half-life impurities are pure β^- or α emitters.

5.5 Storage

5.5.1 General recommendations

For short half-life radionuclides, such as those used in nuclear medicine facilities (see Table 1), storage for decay to the clearance level is almost always the preferred waste management option[11] for economic reasons, safety of workers and protection of the environment. In addition, the activity of radioactive waste is limited. In this case, it is strongly recommended to have an on-site storage of radioactive waste, near the nuclear medicine facility to the management of waste storage and disposal. However, in large hospital complexes, it is possible to have several facilities generating radioactive waste and a centralized radioactive waste facility.

Whatever the type (on-site or centralized), the waste disposal and discharge system depends on the category of the waste. The storage area shall have a system for segregation of radioactive packages. For radiation protection of staff, the storage area should be used only for radioactive wastes and managed to prevent the mixing of waste destined for different routes of disposal.

5.5.2 Specific recommendations for certain waste categories

Cat 4 For nuclear medicine facilities with possible production of radioactive fermentable waste, a designated refrigerated room is strongly recommended or freezers in a specific area.

Cat 5 Wherever possible, radionuclide generators and certain ship packaging of radiopharmaceuticals (e.g. FDG) should be returned to the vendor. IAEA recommends that the same should apply to disused radioactive radiation sources with a radioactive half-life greater than 100 days[11]. These may be sealed radioactive sources or radiopharmaceuticals not administered to a patient with long half-life impurities. Before storage, they shall then be properly packaged using the original packaging material, when available.

5.5.3 Storage area

The size of the storage area should be in line with the segregation of waste, the volume of waste produced, and their decay properties. As recommended in IAEA-TECDOC-1183[11], "the usual radiological protection requirements should apply regarding handling and storage of potentially active wastes. Each facility should define a policy for storage of radioactive wastes. The design of the storage area for radioactive waste should reflect governmental guidance and regulation".

The waste storage area should be sited away from public access, but readily accessible for waste transportation[1]. For radiation protection purposes, it should be constructed of rigid building materials with shielding in line with the radiation emissions and energies to avoid unnecessary exposure. The floor of the storage areas shall be impermeable and waterproof so that contaminated liquids cannot leak or cause contamination outside the storage area or even the building structures, preferably with washing facilities. Foundations should be well drained to prevent standing moisture under the floor of the storage area. Walls should be coated with waterproof paint for easy cleaning. The area should be appropriately ventilated. Appropriate labelling with a radiation symbol and warning of any other hazards should be displayed on the front door. 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 radioactive waste storage facility should be well protected against unauthorized human intrusion. An adequate locking mechanism should be provided to prevent unauthorized access[11].

It may also be necessary to protect against other risks. The storage area should be physically isolated, well away from areas where potentially flammable or explosive materials are located. In order to avoid the risk of fire, non-flammable construction materials should be used when building the facility. The waste storage should take into account potential extremes of temperature which should be avoided[11]. Extreme heat can cause biomedical waste to putrefy greatly increasing infectious hazards, possible bursting of container, and unpleasant odours. In case of storage of fermentable waste, it is strongly recommended to have a freezer adequate for the volume of waste produced and their decay times. As indicated in IAEA-TECDOC-1183[11], "extreme cold is not as critical, however, liquid aqueous waste should be protected from frost to avoid the breaking of aqueous liquid containers. Furthermore, insects and rodents can present a serious threat to containment of packaged radioactive wastes when using bags."

The storage area should have an area for protective equipment and materials to deal with contamination risks, loss of integrity, appropriate radiological monitoring devices, and inventory/log books for traceability of stored waste.

5.6 Disposal and discharge

5.6.1 General recommendations

When considering the proposals for the different waste categories in 4.2.3, it is possible to make different recommendations for waste disposal and discharge. These recommendations are given as examples and should not replace national or local regulatory requirements. Below the clearance levels (see 5.6.2), radioactive waste is no longer considered as such. The distinctive sign of presence of radiological hazard shall be removed. However, the other associated risks are still present inside the bag/container. It may be more practical and safe to dispose of the waste without removing symbols within the container and notifying the final waste processor (incinerator, etc.) that the containers, while labelled internally, are no longer radioactive.

5.6.2 Clearance levels

Setting clearance levels for the discharge of radionuclides is the responsibility of national regulatory authorities to define clearance levels and discharge authorizations. Various clearance levels have been adopted by different countries. These levels do not necessarily have the same unit. They can be expressed as an amount of radioactivity (Bq), concentration of activity (kBq/kg), as a function of the annual limit of intake (ALI), or as a function of a statistically significant difference from background activity or dose rate background. The radioactivity survey of waste packages shall be in conformity with the specified unit for setting clearance levels (see 5.4).

When the clearance levels are based on the activity in a mixture of radionuclides in the packaging, a summation rule shall be applied. Refer to IAEA-TECDOC-1000[10].

Disposal based on dose rate measurement is the simplest way to manage a mixture of radionuclides in the packaging.

The quantitative measurement or estimation of initial activity can result in the choice of the optimized decay period. A final measurement can confirm that this is sufficient to comply with clearance levels. Furthermore, attention should be given to long half-life impurities in short half-life isotopes.

5.6.3 Specific recommendations for certain waste categories

Cat 1 As this category of waste does not present any other associated risks, the waste can then follow the municipal waste collection system.

Cat 2 to 4 It shall be kept in mind that the associated risks (biological/infectious, fermentable and sharps wastes) are always present and may even be increased due to storage time (biological/infectious and fermentable wastes). The waste shall then follow the circuit of the associated risk in conformity with any existing national and local safety standards on such type of waste.

Cat 5 In many countries, it is normal practice for generators to be supplied in reusable Type A packages. The generator is usually decayed for several weeks (3-6 weeks after receipt for molybdenum-99/technetium-99m generators) before being repackaged. In this case, follow national regulation for these types of packages.

Wastes with a half-life exceeding a threshold set by competent authority (e.g., the 100-day threshold recommended by IAEA[11]) can be accumulated in the decay storage area until sufficient volume and/or activity is collected for transportation to a centralized waste processing facility. The packaging in which such wastes are accumulated and the segregation methods used shall reflect the acceptance requirements of the centralized facility.

5.7 Transportation

5.7.1 General recommendations

Transportation of radioactive waste produced by a nuclear medicine facility is normally required when removing waste from the nuclear medicine facility to the storage area and/or a centralized facility (on-site transfer) or to return to vendor (off-site transport). Preparing waste to be transported as well as the transport should follow written rules. It shall be conducted in such a way as to ensure the safety of those involved in the transport operation or by an incident during transport.

5.7.2 On-site transfer

As indicated in 5.5, it is recommended to have an on-site storage area for radioactive waste dedicated to waste coming from the nuclear medicine facility, which is in the same building as the nuclear medicine facility. In this case, the transport is carried out on foot (preferably using a cart or rolling bin) and the management of waste production, transport, storage, and disposal is under the responsibility of the person responsible for radiation protection at the nuclear medicine facility.

Storage can sometimes take place in a centralized storage area in a separate building, requiring transport on foot or by vehicle. In this case, waste management requires the implementation of a transfer of waste management from the nuclear medicine facility to the centralized storage facility. When radioactive waste is transported between rooms or buildings, precautions should be taken to prevent contamination of common places of passage (corridors, hallways, elevators, etc.). Waste containers should be sealed and labelled. The use of carts or rolling bins with secondary containment is preferred. Prior to transfer, specific requirements for radioactive waste should be taken into account. Documentation accompanying radioactive waste to be transferred should contain sufficient information for its recipient to handle the wastes safely, in accordance with requirements of any applicable regulations[11]. As a minimum, the waste origin and category, isotope composition, date of closure, and the corresponding result of the activity or dose rate measurement (see 5.4), date of transport and responsible person should be recorded. The documentation should be handed over by the person that transports the waste to a competent person at the centralized facility for checking prior to the radioactive packaging being unloaded.

5.7.3 Off-site transfer

Off-site transfer should follow national regulation. In the absence of national or local regulations, the packaging requirements for transport of radioactive materials are detailed in IAEA Safety Standards Series No. SSR-6[12], providing general safety principles, activity limits, testing requirements for package types, storage in transit and test and inspection procedures.

6 Radioactive waste management program and quality assurance

6.1 Waste management program

As indicated previously (see Introduction), an effective program for biomedical radioactive waste management is necessary. It is based on the principles of waste prevention and minimization, whilst providing for the protection of personnel and the environment. It should be comprehensive, starting with waste collection to the final clearance and disposal.

The program should be practical, ergonomic, allow for optimization of radiation protection, in accordance with good practice of health professionals. As a first step, it is essential to list the radionuclides used and the manner in which they are used, categories of waste, amounts generated and location of production, as well as the potential circuits for disposal. In particular, this list shall identify the radionuclides with long half-life impurities, as well as their physical characteristics and the circuits adapted to this type of waste.