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

Part 1: Measurement of radioactivity

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

Partie 1: Mesurage de la radioactivité

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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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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

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

Introduction

This document addresses the method for radioactivity measurement, the procedure for determining the storage period, the condition for the clearance of waste contaminated with radioisotopes for medical application based on the initial condition of each type of waste, and the equation to obtain radioactivity from counting measurements using a detector. From the equation, the appropriate duration of storage for the radioactive waste before final disposal can be evaluated.

The amounts of radioisotopes used in medical facilities that are disposed of as waste have been increasing rapidly, due to the development of various technologies applied to diagnosis and radiation treatment using nuclear medicine.

Most of the nuclear medicine applications employ radioisotopes with a short half-life, such as ^{18}F being used in positron emission tomography/computed tomography (PET/CT) diagnosis and ^{99m}Tc being used for a bone or thyroid scan. However, the quantities used in the medical facility can be so large that the disposal of the consequent radioactive waste becomes a serious concern.

The International Atomic Energy Agency (IAEA) proposed criteria for the clearance level of radioactive waste depending on the individual dose (10 μSv/y) and collective dose (1 man-Sv/y) (IAEA Safety Series No 111-P-1.1)[10], and concentration of each nuclide (IAEA RS-G-1.7)[11], and methods for determining the clearance level from the criteria by evaluating the dose or concentration of the radioactive waste on a case-by-case basis.

However, the practical application of the IAEA methods is so complicated that most countries use an alternative method to determine the minimum storage time based on the measurement of radioactivity and radioactive decay for the mainly short-lived radioactive wastes instead of the direct application of IAEA criteria. Therefore, the measurement of radioactivity becomes more significant for obtaining an accurate minimum storage time for each radioactive waste before its disposal.

By considering the current situation regarding the clearance level, this document proposes radioactivity measurement methods useful for establishing the minimum storage duration necessary to attain the applicable clearance level for radioactive wastes, and for verifying wastes have decayed to below the applicable clearance level prior to disposal as non-radioactive waste.

The medical administration of radioactive material is carefully controlled. Therefore, in most cases an estimate of initial activity in waste, sufficient for calculating the minimum storage time for decay to clearance levels, can be derived from knowledge of the administration process, and no initial measurement is necessary or warranted. In such cases the method described in 5.3 can be used to estimate the appropriate storage time.

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

Part 1: Measurement of radioactivity

1 Scope

This document establishes a method for radioactivity measurement and determination of the storage periods of the radioactive wastes produced as a result of the medical application of radioisotopes based on counting measurements using a detector and decay correction of the initial activity concentration of the radioisotopes contained in the waste stream.

It provides a set of controls and measurements for the self-clearance of the radioactive wastes by which the medical facility can be assured of meeting the clearance level.

This document can also be used by testing laboratories or radioactive waste disposal operators.

This document can also be useful for the guidance of the regulatory body.

NOTE Due to the nature of the tests outlined, this document cannot be applied to pure beta emitting nuclides nor to alpha emitting nuclides with low energy gamma rays.

2 Normative references

There are no normative references in this document.

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 http://www.electropedia.org/

3.1
activity
number of spontaneous nuclear disintegrations per unit time.

Note 1 to entry: The activity is expressed in becquerels (Bq).

3.2
bulk
anything greater than the amount of moderate quantities

Note 1 to entry: The term of moderate quantities indicates quantities that “are at most on the order of a ton” of material.

3.3
calibration
set of operations that establishes, under specific conditions, the relationship between values of a quantity and the corresponding values traceable to primary standards

3.4
certified reference material
CRM
reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

3.5
clearance level
value established by the competent authority, expressed in terms of activity, 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

3.6
decay
spontaneous transformation of one radioisotope into one or more different isotopes (known as "decay products" or "daughter products"), accompanied by a decrease in radioactivity of the parent material

Note 1 to entry: The rates of these transformations are unique for each radioisotope and are stated in terms of "half-life," which is the period of time for the activity of a specified isotope to fall to half its original value. The transformations can be a result of electron capture, fission, or the emission of alpha particles, beta particles, or photons (gamma radiation) from the nucleus of an unstable atom.

3.7
medical application
intentional internal or external administration of radioactive material or radiation from radioactive material to patients or research subjects under the supervision of an authorized user

3.8
radioactive waste
radioactive materials at the end of their useful life or in a product that is no longer useful and requires proper disposal

3.9
radioisotope
unstable isotope of an element that decays or disintegrates spontaneously, thereby emitting radiation

Note 1 to entry: Approximately 5 000 natural and artificial radioisotopes have been identified.

3.10
storage container
container in which radioactive waste is secured and stored

4 Fundamentals

4.1 Radioisotopes for medical application

4.1.1 General

Many countries have worked to promote the use of radioactive material in medicine by collaborating with international organizations through projects, programs and agreements. The use of nuclear techniques in medicine has become one of the most widespread peaceful applications of atomic energy.

In modern society, an overview of the two main themes of the application of radioisotopes for medical use includes nuclear medicine and radiotherapy.

4.1.2 Nuclear medicine

The field of nuclear medicine uses a trace amount of radioactive substances called radioisotopes for the diagnosis and treatment of many health conditions such as certain cancers and neurological and heart diseases.

In nuclear medicine, radionuclides are used to provide diagnostic information about the body. The techniques in this field can be broadly divided into two categories: in vivo and in vitro procedures.

a) In vivo[1)]

In vivo non-invasive procedures occur inside the body and account for most of those procedures performed in nuclear medicine. These methods involve the use of radiopharmaceuticals, which are carefully chosen among radioactive materials that are absorbed into a patient's body and, due to their specific chemical properties, target specific tissues and organs, such as the lungs or heart, without disturbing or damaging them.

The material is then identified using a special detector that can detect the small amounts of radiation released from the material, such as a gamma camera, placed outside of the body. The camera can then translate the information into two-dimensional or three-dimensional images of the specific tissue or organ. Among the more well-known and fastest growing of these techniques is positron emission tomography (PET). Practitioners use special instruments called positron emission tomography scanners to obtain scans that track body chemistry and organ function on a molecular level, allowing the identification of more nuanced changes in the health of a patient at an earlier stage than many other diagnostic techniques. PET scans can be combined with other scanning techniques, such as computed tomography, to further enhance the speed, accuracy and usefulness of nuclear medical imaging. Nuclear medicine techniques such as these, unlike traditional X-ray imaging, which depicts anatomical details, reveal how the body functions showing important dynamic physiological or biochemical qualities of the targeted body part. The information produced during such diagnostic procedures frequently supplements static X-ray images, assisting the physician in determining the status and function of different organs, particularly because the physician makes critical decisions and tailors treatment to the patient's needs.

b) In vitro[2)]

In vitro diagnostic procedures are performed outside of the body, such as in a test tube or a culture dish. Within the field of nuclear medicine, procedures such as radioimmunoassay or immunoradiometric assay primarily focus on identifying predispositions to certain health conditions and early diagnosis using genotyping and molecular profiling for various conditions. This can range from identifying changes in cancer cells and tumor markers to measuring and tracking hormones, vitamins and drugs for detecting nutritional and endocrine disorders, as well as, bacterial and parasitic infections such as tuberculosis and malaria.

4.1.3 Radiation therapy

Radiation therapy, or radiotherapy, is a branch of medicine that focuses on the use of radiation to treat cancer and other medical conditions. Radiotherapy is designed to use radiation to target and kill cells. In the case of cancer, when the radiation is applied to a cancerous tumor, or a mass of malignant cells, the targeted cells are damaged and killed, leading to a reduction of the tumor size or, in some cases, the disappearance of the mass. There are primarily three types of radiation therapy treatment options: external beam radiation therapy, brachytherapy and systemic radioisotope therapy.

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1) In vivo: from the Latin for "in one that is living" occurring within the living.

2) In vitro: from the Latin for "in glass" isolated from the living organism and artificially maintained, as in a test tube.

4.2 Application of clearance level

Clearance is defined as the removal of radioactive materials or radioactive objects within authorized practices from any further regulatory control by the regulatory body. Furthermore, the Basic Safety Standard (BSS) of the IAEA states that the clearance levels “shall take account of the exemption criteria and shall not be higher than the exemption levels or defined by the regulatory body”. A footnote indicates that the “clearance of bulk amounts of materials with activity concentrations lower than the guidance exemption levels may require further consideration by the regulatory body”.

In summary, the BSS provides radiological criteria to serve as a basis for the derivation of clearance levels but provides no definitive quantitative guidance on the clearance levels. The activity concentration values developed in Table 1 for use in making decisions on the exemption of bulk materials may be used by regulatory bodies based on the clearance of such materials.

Table 1 — Criteria for radionuclides in bulk amounts of materials

Radionuclides	**Level** (Bq/g)
I-129	0,01
Na-22; Sc-46; Mn-54; Co-56; Co-60; Zn-65; Nb-94; Ru-106[a]; Ag-110m[a]; Sb-125[a]; Cs-134; Cs-137[a]; Eu-152; Eu-154; Ta-182; Bi-207; Th-229; U-232[a]; Pu-238; Pu-239; Pu-240; Pu-242; Pu-244[a]; Am-241; Am-242m[a]; Am-243[a]; Cm-245; Cm-246; Cm-247 [a]; Cm-248; Cf-249; Cf-251; Es-254[a]	0,1
C-14; Na-24; Cl-36; Sc-48; V-48; Mn-52; Fe-59; Co-57; Co-58; Se-75; Br-82; Sr-85; Sr-90[a]; Zr-95[a]; Nb-95; Tc-96; Tc-99; Ru-103[a]; Ag-105; Cd-109[a]; Sn-113[a]; Sb-124; Te-123m; Te-132[a]; Cs-136; Ba-140; La-140; Ce-139; Eu-155; Tb-160; Hf-181; Os-185; Ir-190; Ir-192; Tl-204; Bi-206; U-233; Np-237[a]; Pu-236; Cm-243; Cm-244; Cf-248; Cf-250; Cf-252; Cf-254	1
Be-7; F-18; Cl-38; K-40; K-43; Ca-47; Mn-51; Mn-52m; Mn-56; Fe-52[a]; Co-55; Co-62m; Ni-65; Zn-69m[a]; Ga-72; As-74; As-76; Sr-91[a]; Sr-92; Zr-93; Zr-97[a]; Nb-93m; Nb-97[a]; Nb-98; Mo-90; Mo-93; Mo-99[a]; Mo-101[a]; Tc-97; Ru-97; Ru-105[a]; Cd-115[a]; In-111; In-114m[a]; Sn-125; Sb-122; Te-127m[a]; Te-129m[a]; Te-131m[a]; Te-133; Te-133m; Te-134; I-126; I-130; I-131; I-132; I-133; I-134; I-135; Cs-129; Cs-132; Cs-138; Ba-131; Ce-143; Ce-144[a]; Gd-153; W-181; W-187; Pt-191; Au-198; Hg-203; Tl-200; Tl-202; Pb-203; Po-203; Po-205; Po-207; Ra-225; Pa-230; Pa-233; U-230; U-236; Np-240; Pu-241; Cm-242; Es-254m[a]	10
H-3; S-35; K-42; Ca-45; Sc-47; Cr-51; Mn-53; Co-61; Ni-59; Ni-63; Cu-64; Rb-86; Sr-85m; Sr-87m; Y-91; Y-91m; Y-92; Y-93; Tc-97m; Tc-99m; Rh-105; Pd-109[a]; Ag-111; Cd-115m[a]; In-113m; In-115m; Te-129; Te-131; I-123; I-125; Cs-135; Ce-141; Pr-142; Nd-147; Nd-149; Sm-153; Eu-152m; Gd-159; Dy-166; Ho-166; Er-171; Tm-170; Yb-175; Lu-177; Re-188; Os-191; Os-193; Ir-194; Pt-197m; Au-199; Hg-197; Hg-197m; Tl-201; Ra-227; U-231; U-237; U-239; U-240[a]; Np-239; Pu-234; Pu-235; Pu-237; Bk-249; Cf-253; Es-253; Fm-255	100
Si-31; P-32; P-33; Fe-55; Co-60m; Zn-69; As-73; As-77; Sr-89; Y-90; Tc-96m; Pd-103[a]; Te-125m; Te-127; Cs-131; Cs-134m; Pr-143; Pm-147; Pm-149; Sm-151; Dy-165; Er-169; Tm-171; W-185; Re-186; Os-191m; Pt-193m; Pt-197; At-211; Th-226; Pu-243; Am-242; Cf-246	1 000
Co-58m; Ge-71; Rh-103m; Fm-254	10 000

[a] Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculations (thus requiring only the exemption level of the parent radionuclide to be considered), are listed here:

Fe-52 Mn-52m; Zn-69m Zn-69; Sr-90 Y-90; Sr-91 Y-91m; Zr-95 Nb-95; Zr-97 Nb-97m Nb-97; Nb-97 Nb-97m;

Mo-99 Tc-99m; Mo-101 Tc-101; Ru-103 Rh-103m; Ru-105 Rh-105m; Ru-106 Rh-106; Pd-103 Rh-103m;

Pd-109 Ag-109m; Ag-110m Ag-110; Cd-109 Ag-109m; Cd-115 In-115m; Cd-115m In-115m; In-114m In-114;

Sn-113 In-113m; Sb-125 Te-125m; Te-127m Te-127; Te-129m Te-129; Te-131m Te-131; Te-132 I-132;

Cs-137 Ba-137m; Ce-144 Pr-144 Pr-144m; U-232 Th-228 Ra-224 Rn-220 Po-216 Pb-212 Bi-212 Tl-208;

U-240 Np-240m Np-240; Np-237 Pa-233; Pu-244 U-240 Np-240m Np-240; Am-242m Np-238; Am-243 Np-239; Cm-247 Pu-243; Es-254 Bk-250; Es-254m Fm-254.

For clearance of radioactive material containing more than one radionuclide of artificial origin, on the basis of the levels given in Table 1, the condition for clearance is that the sum of the activity concentrations for individual radionuclides is less than the derived clearance level for the mixture (X_m), determined as given in Formula (1):

$$X_m = \frac{1}{\sum_{i=1}^{n} \frac{f(i)}{X(i)}} \quad (1)$$

where

$f(i)$ is the fraction of activity concentration of radionuclide i in the mixture;

$X(i)$ is the applicable level for radionuclide i as given in Table 1;

n is the number of radionuclides present.

4.3 Classification and characteristics of radioactive waste

Medical radioactive waste tends to contain alpha particles, beta particles and gamma ray emitters. It can be divided into two main classes. In diagnostic nuclear medicine, several short-lived gamma emitters, such as technetium-99m, are used. Many of these can be disposed of by allowing them to decay for a short time before disposal as non-radioactive waste. Other isotopes used in medicine, with half-lives in parentheses, include the following:

a) F-18, used for PET-CT (110 m);

b) I-125, used for biological assays (60 d);

c) I-131, used for thyroid function tests and treating thyroid cancer (8 d);

d) Tl-201, used for heart diagnosis (12 d).

Low-level waste (LLW) is generated by medical facilities and industry. LLW includes paper, rags, syringes, vials, tubes, tools, clothing, filters, and other items that contain radioactive material. Materials that originate from any region of an active area are commonly designated LLW as a precautionary measure even if there is only a remote possibility of being contaminated with radioactive materials. Such LLW typically exhibits no higher radioactivity than one would expect from the amount of naturally occurring radioactive materials present in many common building materials. Some high-activity LLW requires shielding during handling and transport but most LLW is suitable for shallow land burial. To reduce its volume, it is often compacted or incinerated before disposal.

5 Measurement method and procedure

5.1 General

This clause provides methods for radioactivity measurement, and a procedure for determining the storage time necessary to allow radioactive waste to decay to below the applicable clearance levels.

Because there are several types, shapes and volumes of containers used for nuclear medicines in medical facilities, it is not practical to measure the activities of the radioisotopes remaining in all of the containers after use to classify them as a radioactive waste. Therefore, it is reasonable to select the containers most commonly used and measure the activities of the remaining radioisotopes using the certified reference materials (CRMs) disseminated by the national standard laboratory or the secondary standard laboratory that comply to ISO/IEC 17025 accreditation for radioactivity.

The measurement method verifying that the waste has decayed to below the clearance level shall have a minimum detectable activity (MDA) of less than the clearance level, and instrumentation should be calibrated for the types of radiation and energies of the radioiotopes contained in the waste.

The radioactive solutions most commonly used include ^{18}F, ^{51}Cr, ^{67}Ga, ^{85}Sr, ^{99m}Tc, ^{123}I, ^{124}I, ^{125}I, ^{131}I, ^{166}Ho and ^{201}Tl. The measurement protocols are as follow. An an example of the procedure for the clearance of radioactive waste is provided in Annex A and the measurement result of the radioactivity of the radioactive waste is provided in Annex B.

5.2 Procedure for ^{125}I

Currently, the container of ^{125}I is a small tube, and the activity of the remaining solution is measured using a gamma counter. For measurement of ^{125}I activity, the same size and shape as the ^{125}I CRM, specially manufactured by the primary standard institution, is used. The specific activity of the sample, A, is given by Formula (2):

$$A\left(\frac{\text{Bq}}{\text{g}}=\frac{\text{count}}{\text{s}\cdot\text{g}}\right)=\frac{\text{cpm}}{60\frac{\text{s}}{\text{min}}\times eff_{\text{detector}}\times m_{\text{sample}}} \quad (2)$$

where

cpm is the count measurement per minute;

eff_{detector} is the efficiency of the detector;

m_{sample} is the mass of the sample.

The time between the current magnitude of specific activity and that of the clearance level A_{CL} (usually 100 Bq/g) is obtained by the relationship of the decay correction $A_{CL} = A\ (1/2)^n$ or n = ln (A_{CL}/A) / ln (0,5). The storage time N (in half-lives, $T_{½}$) can then be determined by multiplication by a safety factor (1,2) to this time n, i.e. $N = 1{,}2 \times n$. The storage duration necessary for the activity to decay below clearance levels is then n × $T_{½}$.

5.3 Procedure for other radionuclides

For the activity measurement of the other radionuclide, such as ^{18}F, ^{51}Cr, ^{67}Ga, ^{85}Sr, ^{99m}Tc, ^{123}I, ^{124}I, ^{131}I, ^{166}Ho and ^{201}Tl, in containers such as bottles, syringes, vials and tubes, it is recommended to use a Marinelli beaker type CRM and a multichannel analyzer (MCA) using the following procedure, but other measuring methods are also acceptable, if applicable. The solution of the remnants of several radioisotopes is collected in an aqueous solution in another Marinelli beaker whose dimensions are the same as that of the CRM. The bottles containing the remaining radioisotopes are sunk into the solution, and the radioisotopes are mixed with the solution. The reason for sinking several types of bottles of the radioisotopes into the aqueous solution is because the CRM is a homogenous radioactive material. To measure the total activity of the Marinelli beaker containing several types of radioisotopes accurately, this beaker should be approximated as homogeneously as possible, and use of aqueous solution is one of the best options to achieve this.

The measurement of the total activity of the Marinelli beaker is analogous to the activity measurement of ^{125}I with the difference being the use of a Marinelli beaker-type CRM and an MCA for the activity measurement.

If the Marinelli beaker is not available for the measurement of specific activity, the container most often used at the medical facility should be selected as a representative container, a CRM of the same geometry as the container should be obtained from a national laboratory and the storage period should be determined from the same measurement process described in 5.2.

The storage time may also be determined by the same process as in 5.2.

6 Requirements

6.1 Control of the radioactive waste to be stored for disposal

a) Each radioactive waste shall be stored separately and shall not be mixed with any other.

b) The radioactive waste shall be controlled so that it is not dispersed in the process of operation, storage and transportation.

c) Any radioactive waste that is to be buried or incinerated shall be controlled so that it is not negligently recycled.

6.2 Measurement before storage

The following measurements should be made on each bag or container before they are stored in an indoor facility:

a) volume and weight of each bag or container;

b) dose rate at the surface and 1 m from the bag or container;

c) the amount of radioactivity in each bag or container;

d) the surface contamination level on the outside of waste packages.

6.3 Storage of radioactive waste

All types of radioactive wastes, including contaminated liquid radioisotopes, are collected in a storage container and stored in a separate facility for a period of time in the medical facility. In this case, the effects that the stored waste may have on the functionality of systems and on the operation of the waste storage facility should be considered in the design of the facility. It should be ensured that such factors are accounted for using design features and the selection of appropriate materials and maintenance programs. Factors that should be considered include the following:

a) chemical stability of waste form and waste package against corrosion in storage condition;

b) resistance of waste form and waste package against potential damages from radiation, heat, and degradation of organic material;

c) resistance of waste form and waste package against impacts from operational loads or higher impacts due to abnormal storage conditions; and

d) pyrophoric properties and other fire-hazards of the waste form and waste package.

The degree of shielding and its design, if shielding is required, depend on the radiological hazards associated with the stored waste. In addition, the measures for security and access control to the waste storage area are proportional to the waste inventory limits and its radiological hazard levels anticipated, ranging from a simple locked door or cabinet to more sophisticated access control systems.

6.4 Disposal method

The disposal of medical radioactive waste mainly pertains to incineration. Incineration has traditionally been a medical facility's primary method to treat and dispose of medical waste. However, most medical facilities have discontinued the use of their incinerators for one or more of the following reasons: air pollution control requirements, cost of redesigning, national regulation of waste disposal, and expensive maintenance.

The disposal method is not included in the scope of this document.

7 Uncertainty

The uncertainty budget for the determination of the storage period consists of the following:

a) the uncertainty of measuring devices;

b) the uncertainty of the count measurement (repeatability of the measurement);

c) the uncertainty of the certified reference material (CRM) used for the measurement, obtained from the calibration certificate of the CRM;

d) the efficiency of the detector.

The mathematical equations are given in 5.2 and the ensuing uncertainty equation for the measurement of the storage period is given by Formula (3):

$$u_c(N)=\sqrt{u^2(A_r)+u^2(\text{cpm})+u^2(D_{\text{eff}})+u^2(m)+u^2(s\cdot f)} \quad (3)$$

where

$u(N)$	is the uncertainty of the storage time;
$u(A_r)$	is the uncertainty of the activity of the CRM or standard source shown in the certificate;
$u(\text{cpm})$	is the uncertainty of the activity measurement of the sample;
$u(D_{\text{eff}})$	is the uncertainty of the detector efficiency;
$u(k_d)$	is the uncertainty of the mass of the sample;
$u(s{\cdot}f)$	is the uncertainty of the storage factor.

8 Documentation of radioactivity measurement results

The following records need to be prepared and documented for all waste clearances:

a) date;

b) criteria for the clearance level used;

c) location and sub-location;

d) type of radioactive waste measured;

e) instrument used;

f) calibration date and reference source used;

g) background reading (dose rate or count rate);

h) specific activity (including the composition of the radionuclide mixture);

i) the date at which the specific activity falls below the clearance level;

j) name and signature of the person making the measurement.

9 Reporting of results

To check the quality and metrological traceability of the measurement results, the report shall include all the data necessary to validate the analytical measurement methods and to check the quality and metrological traceability of the measurement results. Particularly, it shall enable the determination of all of the implicit measurement and interpretation conditions that do not directly affect the results obtained for the measured radioactive waste. At least the following information should be recorded:

a) time and date of the measurement;

b) radioactive waste identification;

c) radioactive waste weight;

d) calibration standard used;

e) background measurement values used;

f) net measurement results corrected for the background level;

g) uncertainties of the results.

10 Quality control

Performance checks shall be conducted to ensure the conformance of measurements, equipment and facilities to predetermined operational requirements. The laboratory shall have written quality control procedures to verify that the quality of measurements for radioactivity determinations complies with the accuracy requirements. The quality control procedures shall include the following:

a) use of traceable radionuclide reference standards;

b) performance checks of the measurement systems;

c) instrument calibration;

d) review of the procedures, specifications and operating logs;

e) observation of operations and evaluation of quality control data;

f) evaluation of conformance to the performance criteria of this standard;

g) evaluation of quality control data to ensure the long-term consistency of the analytical results.

Annex A
(informative)

Example of the procedure for the clearance of radioactive waste

A.1 Purpose

The purpose of this annex is to establish and generalize the procedure for the clearance of the radioactive waste from the medical application of radioisotopes in the medical facility by adopting the developed procedure for the clearance of radioactive wastes generated by some of the radionuclides currently used as nuclear medicines at Seoul National University Hospital and Korea Cancer Centre Hospital.

A.2 Application

A.2.1 This procedure shall be applied to the following radionuclides in Table A.1. - ^{67}Ga, ^{89}Sr, ^{99}Mo, ^{99m}Tc, ^{125}I, ^{131}I and ^{201}Tl.

A.2.2 This procedure shall be applied to the process from the generation of the radioactive waste as a result of the use of radioactive isotopes to the stage of clearance.

A.2.3 The types of radioactive waste to be released from the regulatory control under this procedure are as follows:

a) beads;

b) coating tubes, PPT;

c) vials (^{67}Ga, ^{89}Sr, ^{99}Mo, ^{99m}Tc, ^{125}I, ^{131}I, ^{201}Tl etc.);

d) ^{99}Mo columns;

e) syringes;

f) other contaminated materials.

A.3 Definition of terms

The definitions of the terms used in this procedure are as follows.

“Collection” refers to the service of collecting the waste furnished in the facilities.

“Collection bag” refers to the bags used for collecting waste in the facilities.

“Collection container” refers to the containers furnished in the facilities; the collection bag is put into the collection container after use.

“Storage” refers to storing the radioactive waste in a certain facility, which is segregated for the purpose of allowing the decay of the radioactivity of the waste until the point of clearance.

A.4 Task and responsibility

A.4.1 Director of the medical facility

The director of the medical facility shall have control over all of the activities related to the process of clearing the radioactive waste.

A.4.2 Radiation safety officer

a) The radiation safety officer shall establish, direct, and supervise the plans for the clearance of the radioactive waste and shall report the results of the clearance to the Director of the medical facility.

b) The radiation safety officer shall ensure the details related to the clearance of radioactive waste and shall maintain appropriate records.

A.5 Collection of radioactive waste

Radioactive waste generated from the use of radioisotopes shall be put into collection bags furnished in the facilities at the time of generation.

A collection bag for the radioactive waste shall be checked for leakage before it is used, and the date of the commencement of its use shall be recorded.

A.6 Methods of collecting waste

When the radioactive waste is collected, the waste shall be classified according to the radionuclides and types.

When only a small amount of radioactive waste is generated, the waste can be stored together with the waste of radionuclides whose storage period is similar with the period categorization shown in Table A.1. Note that in this case, the longest storage period of any of the radionuclides shall be applied.

Table A.1 — Methods of assigning codes for each type of radionuclide and waste

Radionuclide	Code classification of radionuclide	Type of waste	Assorted code number
^{67}Ga	G	Vial	1
^{89}Sr	S	Syringe	2
^{99}Mo	M	Tube	3
^{99m}Tc	T	Bead	4
^{125}I	I	Column	5
^{131}I	E	Cup	6
^{201}Tl	L	Solid waste	7

EXAMPLES In the case of a ^{89}Sr syringe, S-2.

In the case of an ^{125}I tube, I-3.

A.7 Collection bag and container for radioactive waste

The collection bag and container for the radioactive waste shall be made of substances that are spill -proof and non-corrodible. Additionally, the bags also shall be compatible with the chemical nature of the radioactive waste.

The collection bag should be of the correct construction for any additional risks, such as sharps (e.g., needles), and of an appropriate size. The collection container should be large enough to hold numerous bags.

The collection container shall not be easily overturned and shall have a cover so that the container can be closed when it is not in use.

Label tag as shown in Figure A.1 and Figure A.2 shall be affixed on each collection bag and each container.

A.8 Categorization of collection container

Considering the types of radioactive wastes, an adequate quantity of collection containers shall be furnished in the facilities.

The code numbers categorized in Table A.1 shall be assigned to the collection containers, and the number shall be permanently marked so as not to be erased easily.

A.9 Storage of the collection bag of radioactive waste

When the bag is filled with radioactive waste, the opening of the collection bag shall be sealed, and the date of sealing, anticipated date of clearance, volume, and surface dose rate shall be recorded on the "Label tag of Figure A.1 after measurement of the total radioactivity of the bag. The tag shall then be attached to the collection bag.

The sealed collection bags are delivered to the waste storage facilities and stored according to the type of radioactive waste.

Collection bags are stored according to the order of the generation of the waste so that FIFO (first-in, first-out) is possible.

A.10 Clearance of waste

When the storage period of the radioactive waste designated in Table A.2 according to the type of radioactive waste has elapsed, a plan named "Plan for Clearance of Radioactive Waste" for the radioactive waste subject to clearance shall be submitted to the Director of the medical facility. If there is no request from the Director of the medical facility to supplement the plan for clearance, within one month following the submission of the plan, the waste can be managed in accordance with the submitted plan.

Table A.2 — Data when clearance is possible according to the type of nuclide and waste

Code classification	Nuclide	Type of Waste	Storage period	Remark
I-1	^{125}I	Vial	8 months	
I-4	^{135}I	Bead	22 months	
T-2	^{99m}Tc	Syringe	1 week	

NOTE Table A.2 is representative and not definitive i.e. that you should have created your own equivalent of Table A.2 for the materials you hold.

For the clearance, the surface dose rate shall be measured to ensure that the dose rate is less than or equal to the level of the natural background dose rate in the storage area. In measuring the dose rate, caution is required so that the detector is not be affected by other radioactive waste in the vicinity.

For the clearance, the tags of collection bags shall be removed.

A.11 Records related to clearance

Records related to clearance shall be made using the tag in Table A.3 and shall be kept for 5 years from the date of clearance.

Table A.3 — Form for the record of clearance

Serial number	Date of generation	Source of generation	Radionuclide	Content (Types of waste)	Volume	Seal		Clearance			Confirmation	Note
						Date	Surface dose	Date	Surface dose	Method		

Code Classification: I-1-15-001

Date of Generation:

Date of Seal:

Clearance:

Anticipated Date:

Volume:

Surface Dose: (Measurement Date:)

Figure A.1 — Label tag of sign for the collection bag

Code Number: I-1

Content: vial

Figure A.2 — Label tag of sign for the collection container

Annex B
(informative)

Measurement result of the radioactivity of the radioactive waste

B.1 Purpose

The purpose of this annex is to show the radioactivity measurement result of radioactive waste from typical radioisotopes for medical applications. The measurement method and procedure follow this document.

B.2 Results of the radioactive measurement

B.2.1 General

The radioactivity of typical radioisotopes for the purpose of medical application is measured using an MCA (HPGe Detector, Canberra, USA) and gamma counter (Cobra II, USA) in accordance with this document as follows:

B.2.2 Radioisotope ^{18}F

^{18}F is used for PET or PET-CT as a tracer in the form of FDG (fluorodeoxyglucose). Table B.1 shows the results of radioactivity measurements according to the incident types of ^{18}F radioactive waste.

Table B.1 — Radioactivity measurements according to the incident types of ^{18}F radioactive waste

Type of radioactive waste	Syringe cotton ball	Syringe (5 ml)	Syringe (10 ml + 3 Way)
No. of samples (*n*)	20	20	20
(Mean) Specific radioactivity (Bq/g): $\overline{m} \pm \sigma$	362 ± 4	$8{,}14 \times 10^5 \pm 2{,}78 \times 10^5$	$8{,}32 \times 10^4 \pm 3{,}39 \times 10^4$
Uncertainty (%)	2,12	2,31	3,45
(Mean) Storage period to the clearance level (day)	0,11	1,43	1,06

B.2.3 Radioisotope ^{99m}Tc

^{99m}Tc is a radiopharmaceutical used in nuclear medicine for myocardial perfusion imaging. Table B.2 shows the results of radioactivity measurements according to the incident types of ^{99m}Tc radioactive waste.

