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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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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.

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.