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Measurement and prediction of the ambient dose equivalent from patients receiving iodine 131 administration after thyroid ablation —

Part 2: External effective dose of the caregivers after release from the hospital

Mesurage et prévision de l'équivalent de dose ambiant de patients bénéficiant d'un traitement par iode 131 après ablation de la thyroïde —

Partie 2: Dose externe efficace des proches après sortie d'hospitalisation

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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 18310 series can be found on the ISO website

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

ISO 18310 series addresses methods and procedures for measuring ambient dose equivalent from patients administered ^{131}I for thyroid cancer therapy.

Thyroid cancer can be treated by administering radioiodine with the remnants after surgery, because radioiodine selectively accumulates in thyroid tissue to irradiate and kill the cancerous cells. Thyroid cancers are small and are not likely to develop into aggressive malignancies. Earlier diagnosis and treatment can remove these cancers at a time when they are not likely to have spread beyond the thyroid gland.

There are two common practices for the treatment of thyroid cancer: One is a radioiodine administration without thyroid resection. The other is administration after thyroid resection. In recent years, the radioiodine administration after surgery has become more common as radioiodine selectively accumulates in thyroid tissue to irradiate and kill the cancerous cells.

The most commonly used radionuclide for the treatment is ^{131}I. ^{131}I is a radioisotope that emits gamma rays following beta decay. The primary emissions of ^{131}I decay are thus electrons with a maximal energy of 606 keV (89 % abundance, others 248 keV – 807 keV) and 364 keV gamma rays (81 % abundance, others 723 keV). Since the abundance of 364 keV gamma-ray is much greater than other gamma-ray energies, the main contribution to the ambient dose equivalent is from 364 keV gamma-ray. Its radiological half-life is 8,02 d. The iodine is administered orally and is absorbed in the gastrointestinal tract. Most iodine subsequently travels through the blood and is available in the circulation for uptake by the thyroid gland and urinary excretion; the remainder is excreted in faeces, sweat, saliva and breast milk in organic form.[1] For patients who have had their thyroid removed, the retention time in the body is shorter than that of patients who have not had their thyroid removed.

Patients who receive radioiodine treatment for thyroid cancer emit radiation and represent a potential hazard to other individuals. Critical groups among the public are fellow travellers on the patient's trip back home from the hospital, members of the patient's family, close friends, caregivers and comforters.

For the purpose of the ISO 18310 series, this document focus on the determination of the effective dose to the caregiver in the vicinity of the patient treated with radioiodine. It is based on the estimation of the effective dose using a personal dosimeter worn by the caregiver. The uncertainty of the effective dose is also provided.

Measurement and prediction of the ambient dose equivalent from patients receiving iodine 131 administration after thyroid ablation —

Part 2:
External effective dose of the caregivers after release from the hospital

1 Scope

This document addresses the measurement methods, procedures and uncertainty estimation for the measurement, using a personal dosimeter, of the effective dose to the caregiver in the vicinity of the patient treated with radioiodine to ablate the thyroid.

The general requirements for the patient and caregiver and a guidance (see Annex A) for designated expert on instructing caregivers of discharged patients is considered to effectively measure the effective dose to the caregiver in the vicinity of the patient.

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 4037-1, *Radiological protection — X and gamma reference radiation for calibrating dosemeters and doserate meters and for determining their response as a function of photon energy — Part 1: Radiation characteristics and production methods*

ISO 4037-2, *Radiological protection — X and gamma reference radiation for calibrating dosemeters and doserate meters and for determining their response as a function of photon energy — Part 2: Dosimetry for radiation protection over the energy ranges from 8 keV to 1,3 MeV and 4 MeV to 9 MeV*

ISO 4037-3, *Radiological protection — X and gamma reference radiation for calibrating dosemeters and doserate meters and for determining their response as a function of photon energy — Part 3: Calibration of area and personal dosemeters and the measurement of their response as a function of energy and angle of incidence*

ISO 4037-4, *Radiological protection — X and gamma reference radiation for calibrating dosemeters and doserate meters and for determining their response as a function of photon energy — Part 4: Calibration of area and personal dosemeters in low energy X reference radiation fields*

ISO 18310-1, *Measurement and prediction of the ambient dose equivalent from patients receiving iodine 131 administration after thyroid ablation — Part 1: During the hospitalization*

ISO 29661, *Reference radiation fields for radiation protection — Definitions and fundamental concepts*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4037-1 to ISO 4037-4, ISO/IEC Guide 99, ISO 29661 and the following 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
caregiver
individual such as a family member, close friend, or accompanying person who willingly and voluntarily takes care of a discharged patient treated with radioiodine to ablate the thyroid remnants

3.2
calibration
operation under specified conditions that, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

3.3
effective dose
tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body

3.4
electronic personal dosimeter
EPD
electronic device used for continual monitoring with live readout of accumulated radiation dose due to ionizing radiation

3.5
optically stimulated luminescence dosimeter
OSLD
radiation dosimeter used to measure ionizing radiation exposure from electrons trapped between the valence and conduction bands in the crystalline structure of certain minerals by optical stimulation of the material to emit light of a different wavelength

3.6
personal dosimeter
device, such as an *electronic personal dosimeter* (3.4), *optically stimulated luminescence* (3.5), *radiophotoluminescent glass dosimeter* (3.8) or *thermoluminescent dosimeter* (3.9), used for monitoring the personnel cumulative radiation dose due to ionizing radiation

3.7
^{131}I
iodine 131 (^{131}I) that decays with a half-life of 8,02 d with beta and gamma emissions

Note 1 to entry: On decaying, ^{131}I most often (89 % of the time) expend 971 keV of decay energy by transforming into stable ^{131}Xe in two steps with gamma decay following rapidly after beta decay. The primary emissions of ^{131}I decay are beta particles with maximum energy of 606 keV and gamma rays of energy 364 keV. Major application of ^{131}I is for the direct radioisotope therapy to treat hyperthyroidism and some types of thyroid cancer.

3.8
radiophotoluminescent glass dosimeter
RPLD
radiation dosimeter which uses glass compound as the luminescent material

3.9
thermoluminescent dosimeter
TLD
radiation dosimeter used to measure ionizing radiation exposure from electrons trapped between the valence and conduction bands in the crystalline structure of certain minerals by measuring the intensity of light emitted from a crystal in the detector when the crystal is heated

4 General requirements for the release of patient with caregiver

4.1 Discharge criteria

Discharge of an in-patient treated with ^{131}I is permitted only if the dose to family, close friends, and third persons due to the residual activity in the patient is not expected to exceed dose constraints approved by the competent authorities.

The recommendations by the International Commission on Radiological Protection (ICRP) and the standards of International Atomic Energy Agency (IAEA) stipulate a dose limit of 1 mSv/y to the general public and 5 mSv per treatment to relatives, visitors, and caregivers of patients upon release of patients treated with radionuclide from hospitals. Further, ICRP 94[2] recommends applying an annual dose limit of 1 mSv to embryos/fetuses, infants, and children, which is a small group with higher sensitivity, in lieu of a dose limit of 5 mSv per treatment.

The Nuclear Regulatory Commission (USNRC) in the United States indicates in Table 1 of Reference [3] that the derived residual radioactivity of 1.2 GBq or a spatial dose rate of 70 μSv/h at a distance of one metre computes to an effective dose of 5 mSv to other persons at isolation or release of patients from the hospital.

Certain requirements should be met when discharging the patient. The responsible designated expert is to ensure that relevant dose measurements are performed, and that instructions are given to patients, both orally and in writing. The designated expert is to ensure that the patient comprehends the instructions to reduce exposure to other persons, as well as living conditions at home.

4.2 Management procedures of the patient receiving ^{131}I administration

The management procedures for the patient before, during and after treatment with radioiodine are as follows:

a) Isolate the patient and restrict the patient and visitors from entering and exiting the room during the radioactive iodine treatment. During the hospitalization, the patient is not allowed to leave their room, and visitors are not allowed.

b) Increase fluid intake during hospitalization and after discharge. Instruct the patient to urinate often even though there is no urge to urinate and to flush the toilet twice after urination or faecal discharge.

c) While the responsible designated expert continues to process the patient's discharge, the patient may stay in the ward and go home directly after discharge.

d) Instruct the patient either to use personal, separate cutlery and crockery or eat off disposable plates, cups and kitchenware, to use separate towels and bathing goods, and to wash hands clean all the time. Also, they should avoid places with many people such as movie theatres, stores or public transportation.

4.3 Release from the medical facility

As a general rule, the treatment of thyroid cancer using radioiodine is performed only in conjunction with the hospitalization of the patient in some countries. In this case, the discharge of a patient shall be in accordance with the requirements of the regulatory body.

Before discharging a patient from a medical facility, the designated expert shall ensure that the residual activity does not exceed regulatory limits. This shall be done by dose measurements performed at 1 m from the standing patient in accordance with ISO 18310-1.

The instructions of A.2 and A.3 may be given to a released patient and their caregiver.

A.4 is a sample letter of consent by the patient or their legal guardians, including the caregiver.

4.4 Responsibility of the designated expert

The designated expert responsible for the treatment and discharge should ensure that the instructions are understood and followed by the patient and caregiver. The patient should be self-sufficient and capable of co-operating and complying with the instructions. The caregiver is to ensure the patient follows the instruction.

One of the factors to be evaluated for the discharge of patients is the home environment in a socio-economic sense, which should be such as to allow the patients and caregivers to comply with the instructions received. Consideration should be given to the available living space, i.e., the number of rooms in the house, quality of sanitary installations, connection to main sewerage, etc.

5 Measurement of the effective dose to the caregiver

5.1 General

Radioiodine is a common and effective treatment for thyroid cancer. There are, however, significant radiation protection issues associated with treatment. These include emitted radiation and the loss of radioiodine through urine, faeces, sweat, saliva and breast milk. Those at potential risk of being irradiated include members of the public and caregivers with whom the patient may come into close proximity.

5.2 Specifications of the personal dosimeter

The effective dose to the caregiver in the vicinity of the patient treated with radioiodine is measured by a personal dosimeter, such as EPD, OSLD, RPLD or TLD.

The personal dosimeter should have a uniform energy response for the energies of ^{131}I and have a minimum detectable value of 0,01 mSv. The dosimeter should be analysed by an approved dosimetry service in accordance with local regulations.

5.3 Measurement of the effective dose to the caregiver

Procedures for the caregiver using a personal dosimeter after release from the hospital shall be performed as follows:

a) Attach a personal dosimeter, which has a uniform energy response for the energies of ^{131}I, to the chest of the caregiver (e.g. husband, wife or comforter).

b) The caregiver should always wear the personal dosimeter when with the patient.

c) The patient should follow instruction given by the hospital after returning home (see A.3).

d) The caregiver should not be in contact with or near the patient except when providing normal care, for example, serving of meals or administering medication.

e) The caregiver should sleep in a separate bed room.

The caregiver should return to the hospital on a designated date to turn in the dosimeters.

The detailed procedure for measuring the effective dose to the family of the patient receiving ^{131}I administration is given in A.1.

The measurement results for the effective dose to the caregiver are shown in Annex B.

6 Quality control

The personal dosimeter shall be calibrated periodically by a laboratory conforming the requirements of ISO/IEC 17025. As per the Bureau International des Poids et Mesures (BIPM) report, the stability of the calibration coefficient of the personal dosimeter shall be maintained within 5,0 %.

7 Uncertainty

The uncertainty, *U*, for the determination of the measurement of the effective dose from patients administered with ^{131}I consists of the following Formula (1):

$$u_c(H_c)=\sqrt{u^2(N_r)+u^2(M)+u^2(r)+u^2(K)+u^2(\Gamma)+u^2(Q_0)+u^2(\lambda)+u^2(T_r)+u^2(T_m)} \quad (1)$$

where

$u(N_r)$ uncertainty of calibration factor of the detector from the calibration certificate;

$u(M)$ uncertainty of measurement of the effective dose for ^{131}I;

$u(r)$ uncertainty of the ratio of the conversion coefficients between ^{131}I obtained from the interpolation of photon energy versus conversion coefficient fit function and the reference radiation;

$u(K)$ uncertainty of positioning of the chamber for ^{131}I;

$u(Q_0)$ uncertainty of initial administration dosage of ^{131}I;

$u(T_r)$ uncertainty of admission period;

$u(T_m)$ uncertainty of nursing period;

$u(\lambda)$ uncertainty of effective removal constant of ^{131}I;

$u(\Gamma)$ uncertainty of patient rate coefficient.