ISO/TC 85/SC 2 standards for staff radiation protection in medicine

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ISO/TC 85/SC 2
Programme

1. Background
2. Standards for occupational internal dosimetry
3. Standards for occupational external dosimetry
4. Others standards for staff and public radioprotection in medical applications of ionizing radiation
5. Conclusions
The ISO system

Network of 163 national standardization bodies

ISO develops international standards for products, services, processes, materials and systems and for conformity assessment, managerial and organizational practice.

A standard is a document, established by consensus and approved by a recognized body, that provides, for common and repeated use:

- rules,
- guidelines,
- characteristics for activities or for their results,

For the achievement of the optimum degree of order in a given context.
ISO/TC 85/SC 2

TC 85 “Nuclear energy, nuclear technologies and radiological protection”

SC 2 develops standards to protect:
- people (workers, patients, members of the public)
- the environment

against all sources of ionising radiations in planned, existing or emergency exposure situations linked to:
- nuclear activities,
- medical activities,
- industrial activities,
- research activities
- natural radiation sources (radon, cosmic radiation)
ISO/TC 85/SC 2

Medical applications of ionizing radiation

harmonizes and promotes standards supporting professionals and regulators in the context of:

- Increasing demand for the protection of the patient, the public and the workers as well as the protection of the environment
- Huge number of users (more or less educated in R.P.), and more and more sophisticated technologies

includes standards for:

- external and internal individual monitoring of the staff,
- patient dosimetry and related protocols in clinical applications
- shielding systems
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Monitoring of workers occupationally exposed to a risk of internal contamination with radioactive material

offers guidance for:

- decision whether a monitoring programme is required for workers exposed to the risk of internal contamination by radioactive substances
- how it should be designed: compatible goals and minimum requirements
ISO 27048:2011

Dose assessment for the monitoring of workers for internal radiation exposure

- specifies the minimum requirements for the evaluation of data from the monitoring in order to achieve acceptable levels of reliability in internal dose assessment

- provides procedures and assumptions for the standardised interpretation of monitoring data

- allows the quantification of exposures for the documentation of compliance with regulations and radiation protection programmes
ISO 16637:2016

Monitoring and internal dosimetry for staff members exposed to medical radionuclides as unsealed sources

application of the general standard ISO 20553 to the staff of a nuclear medicine department

specifies the minimum requirements for the design of professional programmes to monitor workers exposed to the risk of internal contamination via inhalation by the use of radionuclides as unsealed sources in nuclear medicine imaging and therapy departments
ISO 28218:2010

**Performance criteria for radiobioassay**

- Provides criteria for quality assurance and control, and evaluation of performance of radiobioassay service laboratories.

- It presents guidance for *in vivo* radiobioassay and *in vitro* radiobioassay (monitoring data).
ISO 23588 (in development)

- **General requirements for performance testing for *in vivo* monitoring**

- will be applicable to programs meant to test the quality and capability of the participating laboratories operating *in vivo* detection systems.

- will specify minimum requirements for proficiency tests and intercomparison exercises.

- will cover technical (e.g. selection of radionuclides and phantoms, traceability of activities), management (e.g. announcement, realisation of the measurements, transportation, reporting) and data analysis aspects.
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ISO 15382:2015

Procedures for monitoring the dose to the lens of the eye, the skin and the extremities

applicable to the workers particularly concerned by risk of exposition to the hand during injection of radiopharmaceuticals and interventional radiology procedure

provides procedures for monitoring the dose to the skin, the extremities, and the lens of the eye in planned exposure situations:
- guidance for the need and the design of a monitoring program (type and positioning of the dosemeter according to the nature of the exposure)
- assessment and analyse of skin, extremity, and lens of the eye doses

Laurent Zylberman/Graphix-Images/Médiathèque IRSN
ISO 14146:2018

Criteria and performance limits for the periodic evaluation of dosimetry services

- Evaluation of external dosimetry service

- specifies the criteria and the test procedures for the periodic verification of the performance of services supplying dosemeters.

- It covers all types dosemeters needing laboratory processing (e.g. thermoluminescent, optically stimulated luminescence, radiophotoluminescent, track detectors or photographic-film dosemeters)
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ISO 19461-1:2018

_measurement for the clearance of waste contaminated with radioisotopes for medical application - Part 1: Measurement of radioactivity_

- establishes the method of radioactivity measurement and determination of the storage periods of the radioactive wastes produced as a result of medical application of the radioisotopes in nuclear medicine

- based on counting measurements using a detector and decay correction from the initial activity concentration of the radioisotopes contained in the waste stream.

- provides a set of controls and measurements for the self-clearance of the radioactive wastes meeting the clearance level.
ISO 19461-2 (under development)

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

- will address management of solid biomedical radioactive waste from its generation to final clearance and disposal

- will provide for the main radioisotopes used in nuclear medicine facility guidance for:
  - sorting, collection, packaging and labelling,
  - the radioactivity survey and decay storage,
  - clearance levels, transportation if necessary
ISO 18310-1:2017

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

- guidance to assess the dose to persons close to the patient treated with radioiodine (patients nearby and caregivers)

- estimation of the ambient dose equivalent rate using ionization chamber base dosimetry:
  - measurement methods,
  - calibration of ionization chamber
  - uncertainty estimation
ISO 18310-2 (under development)

Part 2: After release from the hospital

on the ambient dose equivalent from patients after treatment for thyroid cancer by $^{131}$I

will address the measurement methods, procedures and uncertainty estimation for the measurement of the effective dose equivalent to the caregiver in the vicinity of the patient treated with radiiodine to ablate the thyroid using a personal dosimeter, after release of the patient from the hospital.
ISO 16645:2016

*Medical electron accelerators - Requirements and recommendations for shielding design and evaluation*

- to be used as a general framework complementary to the other international standards (IEC and IAEA).

- covers the aspects relating to:
  - regulations,
  - shielding design goals and other design criteria,
  - role of the manufacturers, of the radiation protection officer or qualified expert and interactions between stakeholders,
  - radiations around a linear accelerator,
  - shielding for conventional and special devices (including shielding materials and transmission values, calculations for various treatment room configurations, duct impact on radiation protection),
  - radiological monitoring (measurements).
Dosimetry for the patient

- Others published ISO standards deal with clinical dosimetry for the patient

- ISO 21439:2009 “Clinical dosimetry -- Beta radiation sources for brachytherapy”

- ISO 28057 “Dosimetry with solid thermoluminescence detectors for photon and electron radiations in radiotherapy”. Describes rules for the procedures, applications, and systems of thermoluminescence dosimetry (TLD) for dose measurements according to the probe method.
Conclusion

- ISO has developed different standards for occupational radioprotection in medicine including guidance for the monitoring of external and internal exposure.

- These standards represent a high level of technical consensus.

- They enable regulatory authorities all over the world to facilitate the implementation of basic radiological protection standards established by relevant bodies at the international (e.g. IAEA) or the regional (e.g. European Commission) level.

The published standards can be purchased via ISO/TC85/SC2 web site: https://www.iso.org/committee/50280.html