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Radiological protection — Criteria and performance limits for the periodic evaluation of dosimetry services

Radioprotection — Critères et limites de performance pour l'évaluation périodique des services de dosimétrie

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of the 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, *Radiological protection*.

This second edition of ISO 14146 cancels and replaces the first edition (ISO 14146:2000) of which it constitutes a technical revision. The main change with respect to the previous edition is the inclusion of beta and neutron radiation as well as eye, extremity and area dosemeters.

Radiological protection — Criteria and performance limits for the periodic evaluation of dosimetry services

1 Scope

The quality of a supplier of a dosimetry service depends on both the characteristics of the approved (type-tested) dosimetry system[1)] and the training and experience of the staff, together with the calibration procedures and quality assurance programmes.

This document specifies the criteria and the test procedures to be used for the periodic verification of the performance of dosimetry services supplying personal and/or area dosemeters.

An area dosemeter can be a workplace dosemeter or an environmental dosemeter.

The performance evaluation can be carried out as a part of the approval procedure for a dosimetry system or as an independent check to verify that a dosimetry service fulfils specified national or international type test performance requirements under representative exposure conditions that are expected or mimic workplace fields from the radiological activities being monitored.

This document applies to personal and area dosemeters for the assessment of external photon radiation with a (fluence weighted) mean energy between 8 keV and 10 MeV, beta radiation with a (fluence weighted) mean energy between 60 keV and 3,2 MeV, and neutron radiation with a (fluence weighted) mean energy between 25,3 meV (i.e. thermal neutrons with a Maxwellian energy distribution with kT = 25,3 meV) and 200 MeV.

It covers all types of personal and area dosemeters needing laboratory processing (e.g. thermoluminescent, optically stimulated luminescence, radiophotoluminescent, track detectors or photographic-film dosemeters) and involving continuous measurements or measurements repeated regularly at fixed time intervals (e.g. several weeks, one month).

Active dosemeters (for dose measurement) may also be treated according to this document. Then, they should be treated as if they were passive (i.e. the dosimetry service reads their indicated values and reports them to the evaluation organization).

2 Normatives 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, *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 6980-1, *Nuclear energy — Reference beta-particle radiation — Part 1: Methods of production*

ISO 8529-1, *Reference neutron radiations — Part 1: Characteristics and methods of production*

ISO 12789-1, *Reference radiation fields — Simulated workplace neutron fields — Part 1: Characteristics and methods of production*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

1) If this document is applied to a dosimetry system for which no approval (pattern or type test) has been provided, then in the following text approval or type test should be read as the technical data sheet provided by the manufacturer or as the data sheet required by the regulatory authority.

ISO/TS 18090-1, *Radiological protection — Characteristics of reference pulsed radiation — Part 1: Photon radiation*

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

ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

IEC 61267, *Medical diagnostic X-ray equipment — Radiation conditions for use in the determination of characteristics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 29661 and the following apply.

3.1
approved dosemeter
approved dosimetry system
personal or area dosemeter and associated processing system that has been approved or authorized for use by the qualification body

Note 1 to entry: Several dosemeters designs can be operated using the same associated processing system (dosemeter reader, etc.). Then, they are regarded as several dosemeters/dosimetry systems.

3.2
control (background) dosemeter
personal or area dosemeter that provides an estimate of any radiation dose received by the evaluation sample apart from that given by the irradiating laboratory

Note 1 to entry: The control dosemeter provides a means of estimating and eliminating the contribution to the dose from background radiation and that received during the time between zeroing and read out, i.e. the dose during handling, transportation.

3.3
dosemeter
dosimetry system
radiation meter designed to measure quantities such as an absorbed dose or a dose equivalent

Note 1 to entry: In a wider sense, this term is used for meters designed to measure other quantities related to radiation such as exposure, fluence, etc. Such use is deprecated.

Note 2 to entry: This apparatus may require a separate reader to read out the absorbed dose or dose equivalent.

3.4
dosimetry service
organization that operates a personal and/or area dosimetry system which includes the evaluation of the reading of dosemeters after their use and includes:

— providing the user with dosemeters;

— recording the results;

— reporting the results to the user.

Note 1 to entry: The dosimetry service fulfils basic quality management and independency requirements if it fulfils the requirements stated in ISO/IEC 17025.

Note 2 to entry: The user includes not only external clients but also internal personnel who wear dosemeters provided by their own organization and are engaged in radiation protection activities inside or outside the organization. The same quality of dosimetry service which is provided to external users is also provided to organizations' employees (internal users), in accordance with their own quality management system.

3.5
evaluation sample
randomly selected representative group of personal or area dosemeters used to evaluate the performance of a dosimetry service

Note 1 to entry: The evaluation sample includes dosemeters that are irradiated, remain unirradiated or serve as control dosemeters for the evaluation procedure.

3.6
independent evaluation organization
evaluation organization
independent organization that administers the performance evaluation of dosimetry services and assesses the results

Note 1 to entry: The evaluation organization may include the irradiating laboratory.

Note 2 to entry: The evaluation organization fulfils basic quality management and independency requirements if it fulfils the requirements stated in ISO/IEC 17025.

3.7
independent irradiating laboratory
irradiating laboratory
independent laboratory possessing radiation sources, calibration equipment and associated facilities [all traceable to national (i.e. to primary or secondary) standards] that is able to irradiate dosemeters from the evaluation sample to a high degree of accuracy

Note 1 to entry: The irradiating laboratory fulfils basic quality management and independency requirements if it fulfils the requirements stated in ISO/IEC 17025.

3.8
independent qualification body
qualification body
independent organization empowered by a governmental, regulatory or advisory agency to approve a dosimetry service or authorize the use of a dosimetry system

Note 1 to entry: The qualification body may include the evaluation organization (see 3.6).

Note 2 to entry: The qualification body fulfils basic quality management and independency requirements if it fulfils the requirements stated in ISO/IEC 17025.

3.9
indicated value
G
value of the measurand given directly by a measuring instrument on the basis of its calibration curve

Note 1 to entry: In this document, the indicated value is the one given by the dosimetry systems as the final result of the evaluation algorithm (for example, display of the software, print out) in units of dose equivalent (Sv).

Note 2 to entry: It may be necessary that a measured dose (e.g. by control dosemeters) or a calculated transport and/or background dose be subtracted by the dosimetry service or by the evaluating organization.

3.10
irradiated dose
H_{ref}
conventional quantity value of the dose to which the dosemeter is irradiated

3.11
lower dose limit
H_0
dose below which irradiations should not be performed

3.12
upper dose limit
H_{top}
dose above which irradiations should not be performed

4 Quantities measured

The quantities measured in the evaluation shall be the personal dose equivalent $H_p(10)$, $H_p(3)$ or $H_p(0,07)$, the ambient dose equivalent $H^*(10)$ or the directional dose equivalent $H'(3)$ or $H'(0,07)$ as recommended by the ICRU in Report 47[3] and Report 51[4]. All irradiations for $H_p(d)$ shall be performed on ISO phantoms in accordance with ISO 29661, unless other quantities or other phantoms are specified.

5 Frequency of evaluation

As a general rule, performance evaluations should be repeated at regular intervals, e.g. every one or two years. If any significant change of the dosimetry system or the dosimetry service occurs after an evaluation which may change the performance of the dosimetry service and/or dosimetry system, performing a new evaluation shall be considered.

For approved dosemeters/dosimetry systems only: the qualification body shall be notified of the results of the evaluations and of any significant change of the dosimetry service and/or in the dosimetry system after approval. The qualification body shall recommend a new evaluation when it believes that the modifications may change the performance of the dosimetry service and/or dosimetry system.

6 Test conditions

6.1 Standard test conditions and special handling conditions

The dosimetry service shall supply complete dosemeter badges, i.e. complete dosimeter package worn by a monitored individual or posted as a workplace or environmental monitor. A badge consists of the radiation detector(s), possible supplemental filtering materials, labelling and/or identification typically placed within an enclosure suitable for the environment used and equipped with a means to attach the enclosure to the wearer or within the workplace/environment (e.g., a clip).

The dosimetry service shall not be aware of the radiation qualities and doses used for the irradiations.

One or more dosemeter can be irradiated per irradiation condition.

The quantities which may influence the result, such as ambient temperature, relative humidity, background radiation and contamination by radioactive elements, shall conform to the standard test conditions as given in ISO 29661.

During the performance evaluation cycle, the evaluation sample, including the control dosemeters, shall be stored in environmental conditions that do not affect the measurement results obtained from the dosemeters. Alternative storage conditions may be used in order to mimic real conditions, especially for environmental dosemeters.

The background radiation shall be as small as possible. For an accurate subtraction of the background radiation from the readings of the test dosemeters, the amount of time that the controls and test dosemeters are separated (i.e., the time that it takes to perform the tests) shall be minimized. Ideally, the difference between the accumulated control background and the effective background of the test dosemeters should be less than ±0,01 mSv, or as small as possible.

6.2 Radiation

The radiation sources shall be chosen from those specified in ISO 4037-1 (reference photon radiation fields), ISO 6980-1 (reference beta radiation fields), ISO 8529-1 (reference neutron radiation fields),

ISO 12789-1 [simulated workplace fields with broad energy and angle distributions (e.g., isotropic)], or IEC 61267 (medical diagnostic radiation fields) according to those radiation types for which the system has been approved. In order to mimic real workplace conditions, other radiation fields may be used if qualified reference dose measurements are performed. Mixtures may also be used. Pulsed reference photon radiation fields shall be chosen from those specified in ISO/TS 18090-1 or other specified radiation fields.

Additional reference fields of natural environmental radiation may be chosen to evaluate environmental dosemeters.

NOTE 1 The conventional quantity value for natural environmental radiation can be assessed as described in the literature[6].

NOTE 2 Values for the conversion coefficients from air kerma, K_a to $H_p(3)$ are not contained in ISO 4037 series. They can, however, be found in the literature[7].

NOTE 3 Conversion coefficients from air kerma to the operational quantities for medical diagnostic radiation fields according to IEC 61267 can be determined as described in the literature[7]. Selected values can be found in the literature[8][9][10].

The choice of radiation qualities and angles of incidence should be guided by the following considerations:

— attempts should be made to vary the radiation qualities used for repeated performance evaluations of the same dosimetry system or the same dosimetry service — one radiation quality should be left unchanged from evaluation to evaluation to assess the calibration control;

— the radiation qualities and angles of incidence should be selected from the range of energies and angles of incidence for which all dosimetry systems taking part in the evaluation have been approved;

— the majority of radiation qualities and angles of incidence should be similar to the conditions found in routine radiation surveillance in order to prevent evaluations from emphasizing performance under extreme conditions.

Radiation qualities with broad energy spectra (e.g. the photon "wide spectrum" series and the photon "high air kerma rate" series) can be used only when their spectra ensure that most of the radiation (at least 90 % fluence weighted) is within the range of energies for which the system — or, if several dosimetry systems take part in the evaluation, for which the majority of the dosimetry systems — has been approved.

Mixtures of two or more radiation qualities may be appropriate in order to mimic workplace fields [e.g. two different energies and/or angles of incidence of the same radiation type, or different radiation types, (e.g. beta and photon radiation or photon and neutron radiation)].

6.3 Dose range

Testing shall be consistent with the dose range for which all dosimetry systems taking part in the evaluation have been approved. The choice of the dose values, H_{ref}, should be guided by the following considerations:

— attempts should be made to vary the dose values used for repeated performance evaluations of the same dosimetry system or the same dosimetry service;

— the majority of irradiated doses should be similar to the conditions found in routine radiation surveillance in order to prevent evaluations from emphasizing performance under extreme conditions;

— the dose values should not be less than H_0:

  — 10 µSv for environmental dosemeters measuring $H^*(10)$;

— 0,1 mSv for workplace dosemeters measuring $H^*(10)$ and for whole-body dosemeters measuring $H_p(10)$;

— 0,3 mSv for eye lens dosemeters measuring $H_p(3)$ and for area dosemeters measuring $H'(3)$;

— 1 mSv for extremity and whole body dosemeters measuring $H_p(0,07)$ and for area dosemeters measuring $H'(0,07)$.

Other values of H_0 may be chosen by the evaluation organization if found to be appropriate.

NOTE 1 It is recommended to use at least values of H_{ref} larger than three times the expected background dose.

NOTE 2 Eye lens dosemeters need to be small resulting in small detectors (as they need to be worn near the eye). Therefore, H_0 for $H_p(3)$ cannot be as small as H_0 for $H_p(10)$. Further information on eye lens dosimetry can be found in ISO 15328[1].

— the dose values should not exceed H_{top}:

— 10 Sv for area and personal dosemeters.

The uncertainty of the irradiated dose shall be determined in accordance to ISO/IEC Guide 98-3 (GUM) and shall be, in orientation to ICRP 75[5], less than 8 % (for a 95 % coverage interval). In simulated workplace fields and for neutron irradiations, the uncertainty can be higher but should not be larger than 15 %. If it were larger, it should be considered in Formula 2 to Formula 4.

7 Performance limits

7.1 Limits

7.1.1 Personal and area dosemeters

For each irradiated dosemeter, the quotient R between the measured dose value G and the conventional quantity value H_{ref}, given by the response, as in Formula (1):

$$R = \frac{G}{H_{ref}} \tag{1}$$

shall meet the following criteria between H_0 and H_{top} (see 6.3):

— Criterion 1) For photon radiation with a mean energy of $\bar{E}_{ph} > 10$ keV and for beta radiation with a mean energy of $\bar{E}_{beta} > 0,2$ MeV (easier-to-measure):

$$0,71 \cdot \left(1 - \frac{2 \cdot H_0/1,33}{H_0/1,33 + H_{ref}}\right) \leq R \leq 1,67 \cdot \left(1 + \frac{H_0}{4 \cdot H_0 + H_{ref}}\right) \tag{2}$$

— Criterion 2) For neutron radiation, for photon radiation with a mean energy of $\bar{E}_{ph} \leq 10$ keV, and for beta radiation with a mean energy of $\bar{E}_{beta} \leq 0,2$ MeV (harder-to-measure):

$$0{,}5\cdot\left(1-\frac{2\cdot H_0/1{,}5}{H_0/1{,}5+H_{\mathrm{ref}}}\right)\leq R\leq 2 \tag{3}$$

If mixtures of two or more radiation qualities and or types are used and the above-mentioned harder-to-measure components contribute 20 % or more of the total dose, criterion (2) applies to total dose. Criterion (1) applies for a contribution below 20 %.

NOTE 1 The factors 0,71 and 1,67 (criterion 1) and 0,5 and 2 (criterion 2) limit the maximum deviation of the dosimetry system at high dose values. At the lower limit of the dose range, −90 % and +100 % deviation is allowed.

NOTE 2 The factors 0,71 and 1,67 are similar to the corresponding factors in ICRP 75[5] (0,67 and 1,5).

NOTE 3 Annex A provides graphical illustrations of the performance limits.

NOTE 4 For beta radiation, criterion 2 is valid for Pm-147 radiation. Beta mean energies are given by Behrens[11].

NOTE 5 The criteria are orientated in order to make sure that approved dosimetry systems also pass tests according to this document.

7.1.2 Environmental dosemeters for Cs-137 and environmental radiation

For Cs-137 and environmental radiation for each irradiated dosemeter, the quotient R between the measured dose value G and the conventional quantity value H_{ref}, given by the response, see Formula (1).

$$R=\frac{G}{H_{\mathrm{ref}}}$$

shall meet the following criterion between H_0 and H_{top}:

$$0{,}8\leq R\leq 1{,}33 \tag{4}$$

For other radiation qualities, the limits of 7.1.1 apply.

7.2 Approval criterion

The criteria stated in 7.1 are valid for a coverage interval with a coverage probability of 95 %. A maximum of one-tenth of the dosemeters irradiated may exceed the limits.

NOTE 1 A coverage probability of 95 % corresponds to one-twenties. With this, the uncertainty of the delivered dose (see last sentence of 6.3) is taken into account.

The dosimetry service shall fulfil the requirements stated in ISO/IEC 17025.

8 Operational procedures

8.1 Evaluation sample size

For each dosimetry system taking part in the evaluation, at least 13 dosemeters shall be included in the evaluation sample. At least ten dosemeters to be irradiated under the conditions stated in Clause 6 and at least three dosemeters shall be left unirradiated: at least two of them as control dosemeters for the measurement of the sum of the background dose and the dose during transport and at least one of them as spare in case of failure during the irradiation or breakage. One or more dosemeter can be irradiated per irradiation condition.

If the performance evaluation is carried out less frequently than once per year, then the minimum number of irradiated dosemeters may be increased.

8.2 Evaluation procedure

The dosimetry service shall confirm that the dosemeters submitted for evaluation are representative of those supplied routinely to users.

To ensure that the processing of the evaluation dosemeters is carried out in exactly the same way as for the dosimetry service's normal customers, the evaluation organization may send a representative to select the dosemeters and to observe that no special effort is made in processing them.

The evaluation organization may obtain the dosemeters and communicate with the dosimetry service through a "dummy customer" and thus prevent the dosimetry service from handling the evaluation sample differently, which could influence the evaluation results.

8.3 Evaluation sequence

Evaluation is normally carried out in the following 6 to 7 steps:

a) the dosimetry service orders the evaluation or the evaluation organization initiates the evaluation with or without the dosimetry service's knowledge;

b) the evaluation organization prepares the evaluation schedule, obtains the dosemeters from the dosimetry service and arranges for irradiation of the dosemeters;

c) the dosimetry service processes the dosemeters using normal practices and reports the measured doses and associated uncertainties to the evaluation organization; the dose shall be reported with enough significant digits in order to rule out rounding effects (this may be in contrast to the normal practice);

NOTE Guidance for the determination of the uncertainty of the measured dose can be found in IEC/TR 62461[2].

d) in contrast to the normal practice, it may be necessary that a measured (e.g. by control dosemeters) or calculated transport or background dose be subtracted by the dosimetry service or by the evaluation organization. This procedure may be different from routine procedures of dosimetry services. The information about the procedure of the transport or background dose correction has to be stated by the dosimetry service;

e) the evaluation organization can supply further information on the radiation fields for the correct dose measurement; this can be, for example, of special importance for neutron albedo dosemeters; the extra information on the radiation fields supplied to the dosimetry service shall be included in the test report of the results;

f) the evaluation organization analyses the evaluation results and associated uncertainties and submits them to the dosimetry service and/or qualification body;

g) the evaluation organization maintains the documentation, which shall at least include the following information for each dosemeter:

- a unique identifier for each dosemeter tested;
- the radiation type, energy and the angle of incidence;
- the ambient conditions during the irradiation;
- the phantom used (for personal dosemeters only);
- the values of the delivered dose with associated uncertainties and measured doses with associated uncertainties. The principles used for determining the associated uncertainties should be stated;
- the response R.

9 Test report

The qualification body or, if the qualification body is not involved, the evaluation organization shall inform the dosimetry service of the results.

The qualification body or, if the qualification body is not involved, the evaluation organization shall deem competent each dosimetry service which is able to show compliance with the performance limits stated in Clause 7 for each dosimetry system examined.

The qualification body or, if the qualification body is not involved, the evaluation organization shall provide the dosimetry service with a test report which specifies at least

— the dosimetry service's name,

— the dosimetry system, quantity and type of radiation for which it has been approved,

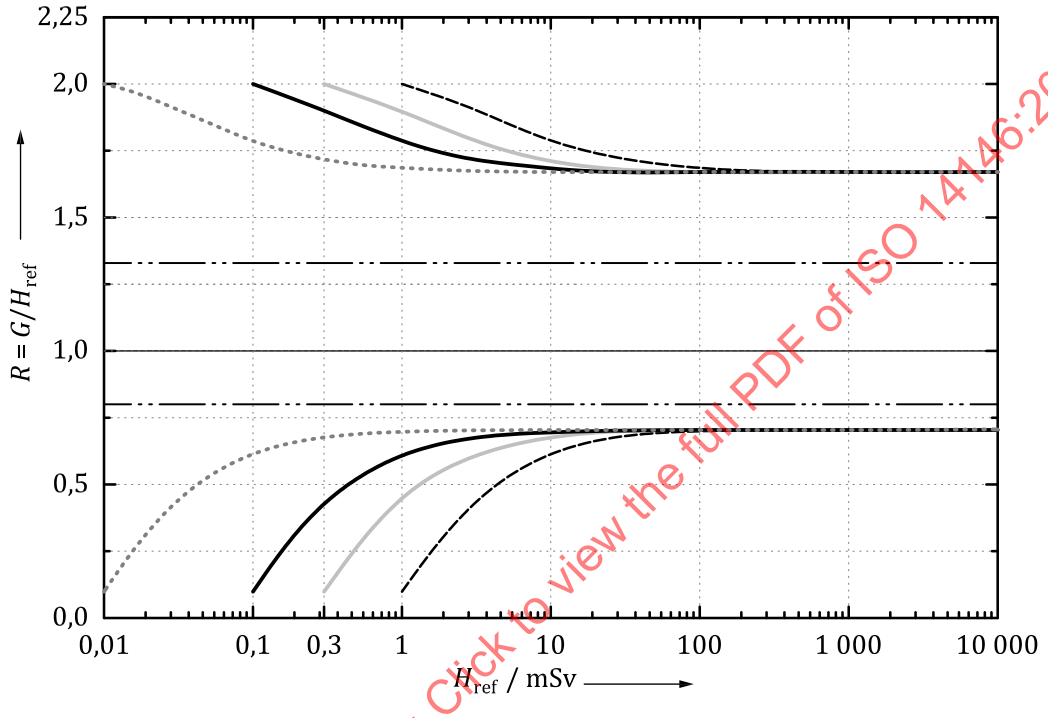
— a statement on how the uncertainties of the delivered doses were considered, and

— the information listed in 8.3 g.

Annex A
(informative)

Graphical illustrations of the performance limits

In Figures A.1 and A.2, the performance limits stated in Clause 7 are illustrated.



Key

environmental $H^*(10)$ dosemeters: 0,01 mSv to 10 Sv

environmental $H^*(10)$ dosemeters: Cs-137 and environmental radiation: 0,01 mSv to 10 Sv

workplace $H^*(10)$ and whole-body $H_p(10)$ dosemeters: 0,1 mSv to 10 Sv

area $H'(3)$ and eye lens $H_p(3)$ dosemeters: 0,3 mSv to 10 Sv

extremity and whole-body $H_p(0,07)$ and area $H'(0,07)$ dosemeters: 1 mSv to 10 Sv

Figure A.1 — Performance limits for photons with >10 keV and betas with >0,2 MeV (criterion 1)