SLOVENSKI STANDARD
SIST EN ISO 19238:2023

01-november-2023

Radiološka zaščita - Merila za delovanje laboratorijev, ki izvajajo biološko dozimetrijo s citogenetiko - Diecentrična analiza (ISO 19238:2023)

Radiological protection - Performance criteria for service laboratories performing biological dosimetry by cytogenetics - Dicentric assay (ISO 19238:2023)

Strahlenschutz - Durchführungskriterien für Dienstleistungslaboratorien zur Anwendung der biologischen Dosimetrie mittels zytogenetischer Verfahren - Dizentrische Chromosomenanalyse (ISO 19238:2023)

Radioprotection - Critères de performance pour les laboratoires de service pratiquant la dosimétrie biologique par cytogénétique - Dénombrement des dicentriques (ISO 19238:2023)

Ta slovenski standard je istoveten z: **EN ISO 19238:2023**

ICS:

13.280	Varstvo pred sevanjem	Radiation protection
17.240	Merjenje sevanja	Radiation measurements

SIST EN ISO 19238:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 19238

September 2023

ICS 13.280; 17.240

Supersedes EN ISO 19238:2017

English Version

Radiological protection - Performance criteria for service laboratories performing biological dosimetry by cytogenetics - Dicentric assay (ISO 19238:2023)

Radioprotection - Critères de performance pour les laboratoires de service pratiquant la dosimétrie biologique par cytogénétique - Dénombrement des dicentriques (ISO 19238:2023)

Strahlenschutz - Durchführungskriterien für Dienstleistungslaboratorien zur Anwendung der biologischen Dosimetrie mittels zytogenetischer Verfahren - Dizentrische Chromosomenanalyse (ISO 19238:2023)

This European Standard was approved by CEN on 12 August 2023.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 19238:2023) has been prepared by Technical Committee ISO/TC 85 "Nuclear energy, nuclear technologies, and radiological protection" in collaboration with Technical Committee CEN/TC 430 “Nuclear energy, nuclear technologies, and radiological protection” the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2024, and conflicting national standards shall be withdrawn at the latest by March 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 19238:2017.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

The text of ISO 19238:2023 has been approved by CEN as EN ISO 19238:2023 without any modification.

INTERNATIONAL STANDARD

ISO 19238

Third edition
2023-08

Radiological protection — Performance criteria for service laboratories performing biological dosimetry by cytogenetics — Dicentric assay

Radioprotection — Critères de performance pour les laboratoires de service pratiquant la dosimétrie biologique par cytogénétique — Dénombrement des dicentriques

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 document 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 of 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 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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 430, *Nuclear energy, nuclear technologies, and radiological protection*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 19238:2014), of which it constitutes a minor revision.

The main changes are as follows:

— title changed from "*Radiological Protection — Performance criteria for service laboratory performing biological dosimetry by cytogenetics*" to "*Radiological protection — Performance criteria for service laboratory performing biological dosimetry by cytogenetics — Dicentric assay*";

— minor edits to text throughout;

— addition of 8.2.7 on data security plan;

— simplification of laboratory safety requirements including deletion of safety plan to demonstrate that each laboratory shall meet the requirements of their country;

— addition of material related to automated analysis;

— addition of detail in 10.2.3 on scoring first-division metaphases;

— addition of detail in 11.2, Establishment of calibration curve(s);

— addition of details on determining the minimal resolvable dose.

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

The widening use of ionising radiations for medical, industrial, agricultural, research, and military purposes increases the risk of overexposure of radiation workers and individuals of the general population. Biological dosimetry, based on the study of chromosomal aberrations, mainly through the dicentric assay, has become a routine component of accidental dose assessment. Experience with its application in hundreds of cases of suspected or verified overexposures has proven the value of this method and also defined its limitations. It should be emphasized that dicentric chromosome analysis is used as a dosimeter and provides one input into the compendium of information needed for assessment of a radiological incident.

Many studies on animals and humans have shown that one can establish a good correlation between the results obtained in vivo and in vitro, so that in vitro established dose-effect relationships from irradiated blood samples can be used to form calibration curves. The dicentric yield is dependent on radiation quality and dose rate, as well as the circumstances of exposure, for example time since exposure, homogeneity, so information about these variables is important for each investigation. If known, these exposure characteristics are important for refining the aberration dose estimates. The specificity of this technique is enhanced by the fact that generally 1 dicentric is observed per 1 000 metaphase spreads in the normal population, and that this frequency is essentially independent of age and sex. The precision of the technique thus depends on the number of cells observed, the background level, and the calibration curve used. Theoretically, it is possible to detect exposure as low as 0,01 Gy, however, for such low doses, it is necessary to analyse tens of thousands of metaphase spreads. In practice, this level of detection is neither feasible nor necessary. The upper dose detection limits extend well into the range of doses that are lethal to humans.

The primary purpose of this document is to provide a guideline to all laboratories in order to perform the dicentric assay using documented and validated procedures. Secondly, it facilitates the comparison of results obtained in different laboratories, particularly for international collaborations or interlaboratory comparisons. Finally, laboratories newly commissioned to carry out the dicentric assay should conform to this document in order to perform the assay reproducibly and accurately.

This document is written in the form of procedures to be adopted for biological dosimetry for overexposures involving, at most, a few casualties. The criteria required for such measurements usually depends upon the application of the results: radiation protection management, medical management when appropriate, record keeping, and legal requirements. In the special situation of a mass radiation casualty and limited resources, the technique can be applied for emergency triage analysis as described in ISO 21243[1].

A part of the information in this document can be found in other international guidelines and scientific publications, primarily in the International Atomic Energy Agency's (IAEA) Technical Reports series on biological dosimetry[2]. However, this document expands and standardizes the quality assurance and quality control, the criteria of accreditation, and the evaluation of performance. This document is generally compliant with ISO/IEC 17025, with particular consideration given to the specific needs of biological dosimetry. The expression of uncertainties in dose estimations given in this document comply with the ISO guide to the expression of uncertainty in measurement (ISO/IEC Guide 98-1[3]) and the ISO 5725-1[4], ISO 5725-2[5] and ISO 5725-3[6] on accuracy (trueness and precision) of measurement methods and results.

Radiological protection — Performance criteria for service laboratories performing biological dosimetry by cytogenetics — Dicentric assay

1 Scope

This document provides criteria for quality assurance and quality control, evaluation of the performance and the accreditation of biological dosimetry by cytogenetic service laboratories using the dicentric assay performed with manual scoring.

This document is applicable to

a) the confidentiality of personal information, for the requestor and the service laboratory,

b) the laboratory safety requirements,

c) the calibration sources and calibration dose ranges useful for establishing the reference dose-response curves that contribute to the dose estimation from unstable chromosome aberration frequency and the detection limit,

d) the scoring procedure for unstable chromosome aberrations used for biological dosimetry,

e) the criteria for converting a measured aberration frequency into an estimate of absorbed dose,

f) the reporting of results,

g) the quality assurance and quality control, and

h) informative annexes containing sample instructions for requestor (see Annex A), sample questionnaire (see Annex B), sample report (see Annex C), fitting of the low dose-response curve by the method of maximum likelihood and calculating the error of the dose estimate (see Annex D), odds ratio method for cases of suspected exposure to a low dose (see Annex E), a method for determining the decision threshold and detection limit (see Annex F) and sample data sheet for recording aberrations (see Annex G).

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

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 https://www.electropedia.org/