SLOVENSKI STANDARD
SIST EN ISO 19238:2018

01-februar-2018

Radiološka zaščita - Merila za delovanje laboratorijev, ki izvajajo biološko dozimetrijo s citogenetiko (ISO 19238:2014)

Radiological protection - Performance criteria for service laboratories performing biological dosimetry by cytogenetics (ISO 19238:2014)

Radioprotection - Critères de performance pour les laboratoires de service pratiquant la dosimétrie biologique par cytogénétique (ISO 19238:2014)

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ICS:

13.280	Varstvo pred sevanjem	Radiation protection
17.240	Merjenje sevanja	Radiation measurements

SIST EN ISO 19238:2018 **en,fr,de**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 19238

October 2017

ICS 13.280; 17.240

English Version

Radiological protection - Performance criteria for service laboratories performing biological dosimetry by cytogenetics (ISO 19238:2014)

Radioprotection - Critères de performance pour les laboratoires de service pratiquant la dosimétrie biologique par cytogénétique (ISO 19238:2014)

This European Standard was approved by CEN on 13 September 2017.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

The text of ISO 19238:2014 has been prepared by Technical Committee ISO/TC 85 “Nuclear energy, nuclear technologies, and radiological protection” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 19238:2017 by 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of an identical text or by endorsement, at the latest by April 2018, and conflicting national standards shall be withdrawn at the latest by April 2018.

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Endorsement notice

The text of ISO 19238:2014 has been approved by CEN as EN ISO 19238:2017 without any modification.

INTERNATIONAL STANDARD

ISO 19238

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

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

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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 documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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The committee responsible for this document is ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

This second edition cancels and replaces the first edition (ISO 19238:2004), of which it constitutes a minor revision.

Introduction

The wide 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 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 proved the value of this method and also defined its limitations. It should be emphasized that cytogenetic analysis is used as a dosimeter and provides one input into the compendium of information needed for assessment of a radiological accident.

Many studies in animals and man 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 as calibration curves. The dicentric yield is dependent on radiation quality and dose rate so that information about these variables needs to be established for each investigation. If known, these exposure characteristics are important for refining the 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 approximatively 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 these very 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 limits to dose detection extend well into the range of doses that are lethal to humans.

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

This International Standard 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 will usually depend 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. The standard recommended scoring criteria would then be relaxed as appropriate to the situation.

A part of the information in this International Standard is contained in other international guidelines and scientific publications, primarily in the International Atomic Energy Agency's (IAEA) Technical Reports Series on Biological Dosimetry. However, this International Standard expands and standardizes the quality assurance and quality control, the criteria of accreditation, and the evaluation of performance. This International Standard 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 International Standard comply with the ISO guide to the expression of uncertainty in measurement (ISO/IEC Guide 98-1) and the ISO 5725 on accuracy (trueness and precision) of measurement methods and results.

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

1 Scope

This International Standard provides criteria for quality assurance and quality control, evaluation of the performance, and the accreditation of biological dosimetry by cytogenetic service laboratories.

This International Standard addresses

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

b) the laboratory safety requirements,

c) the calibration sources and calibration dose ranges useful for establishing the reference dose-effect curves that contribute to the dose estimation from chromosome aberration frequency and the minimum resolvable doses,

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,

h) informative annexes containing sample instructions for customer, sample questionnaire, sample of report, fitting of the low dose-response curve by the method of maximum likelihood and calculating the error of dose estimate, odds ratio method for cases of suspected exposure to a low dose, and sample data sheet for recording aberrations.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
acentric
terminal or interstitial chromosome fragment of varying size, referred to as an excess acentric fragment when it is formed independently of a dicentric or centric ring chromosome aberration

2.2
background level
spontaneous frequency (or number) of chromosome aberrations recorded in control samples or individuals

2.3
bias
statistical sampling or testing error caused by systematically favouring some outcomes over others

2.4
centric ring
aberrant circular chromosome resulting from the joining of two breaks on separate arms of the same chromosome

Note 1 to entry: It is generally accompanied by an acentric fragment.

