

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

ICS 13.280; 17.240

National foreword

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Radiation 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 19238 was prepared by Technical Committee ISO/TC 85, *Nuclear energy*, Subcommittee SC 2, *Radiation protection*.

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 emphasised 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 on animals and man have shown that one could 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 intercomparison. Finally, laboratories newly commissioned to carry out the dicentric assay should conform to this International Standard in order to perform it reproducibly and accurately.

The 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 (GUM) and the ISO 5725 on accuracy (trueness and precision) of measurement methods and results.

Radiation 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 allowing the dose estimation from chromosome aberration frequency, and the minimum detection levels,
- 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 examples of a questionnaire, instructions for customers, a data sheet for recording aberrations and a sample report.

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

NOTE When it is formed independently of a dicentric or centric ring chromosome aberration, it is usually referred to as an excess acentric

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