ICS 13.280 SLOVENSKÁ TECHNICKÁ NORMA August 2021

STN	**Rádiologická ochrana Kritériá spôsobilosti laboratórií používajúcich translokačnú skúšku fluorescenčnej in situ hybridizácie (FISH) na hodnotenie expozície ionizujúceho žiarenia (ISO 20046: 2019)**	**STN EN ISO 20046** 40 1412

Radiological protection - Performance criteria for laboratories using Fluorescence In Situ Hybridization (FISH) translocation assay for assessment of exposure to ionizing radiation (ISO 20046:2019)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/21

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 20046

February 2021

ICS 13.280

English Version

Radiological protection - Performance criteria for laboratories using Fluorescence In Situ Hybridization (FISH) translocation assay for assessment of exposure to ionizing radiation (ISO 20046:2019)

Radioprotection - Critères de performance pour les laboratoires utilisant l'analyse des translocations visualisées par hybridation in situ fluorescente (FISH) pour évaluer l'exposition aux rayonnements ionisants (ISO 20046:2019)

Strahlenschutz - Leistungskriterien für Laboratorien, die den Fluoreszenz-in-situ-Hybridisierungs-(FISH)-Translokationstest zur Bewertung der Exposition gegenüber ionisierender Strahlung verwenden (ISO 20046:2019)

This European Standard was approved by CEN on 18 January 2021.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

The text of ISO 20046:2019 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 20046:2021 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of an identical text or by endorsement, at the latest by August 2021, and conflicting national standards shall be withdrawn at the latest by August 2021.

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Endorsement notice

The text of ISO 20046:2019 has been approved by CEN as EN ISO 20046:2021 without any modification.

INTERNATIONAL STANDARD

ISO 20046

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Radiological protection — Performance criteria for laboratories using Fluorescence In Situ Hybridization (FISH) translocation assay for assessment of exposure to ionizing radiation

Radioprotection — Critères de performance pour les laboratoires utilisant l'analyse des translocations visualisées par hybridation in situ fluorescente (FISH) pour évaluer l'exposition aux rayonnements ionisants

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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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This document was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies and radiological protection*, Subcommittee SC 2, *Radiological protection*.

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 purpose of this document is to define the use of fluorescent in situ hybridization (FISH) for chromosome translocation analysis on human peripheral blood lymphocytes for biological dosimetry of exposure to ionizing radiation. Biological dosimetry, based on the study of chromosomal aberrations, mainly the dicentric assay, has become a routine component of accidental dose assessment. Dicentric aberrations, however, disappear with time after exposure, making this assay useful only in the short term after exposure. Translocations, however, are more stable, allowing dose estimates to be made long times after exposure or after protracted exposures.

This document provides a guideline for performing the translocation assay by FISH for dose assessment using documented and validated procedures. The minimum requirements for testing translocation yield in peripheral blood lymphocytes, by precisely defining the technical aspects of staining chromosomes (number of chromosomes and types of painting), selecting types of aberrations and cells, scoring aberrations, converting aberration yield to dose, statistical considerations, problems related to heterogeneous, chronic or delayed exposures and extrapolation to full genome are described. Dose assessment using the FISH assay has relevance in medical management, radiation-protection management, record keeping, and medical/legal requirements.

A part of the information in this document 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 document expands and standardizes the quality assurance and quality control and the evaluation of performance.

INTERNATIONAL STANDARD ISO 20046:2019(E)

Radiological protection — Performance criteria for laboratories using Fluorescence In Situ Hybridization (FISH) translocation assay for assessment of exposure to ionizing radiation

1 Scope

The purpose of this document is to provide criteria for quality assurance (QA), quality control (QC) and evaluation of the performance of biological dosimetry by cytogenetic service laboratories.

This document addresses:

a) the responsibilities of both the customer and the laboratory;

b) the confidentiality of personal information, for the customer and the laboratory;

c) the laboratory safety requirements;

d) sample processing; culturing, staining and scoring, including the criteria for scoring for translocation analysis by FISH;

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

f) the scoring procedure for translocations stained by FISH used for evaluation of exposure;

g) the criteria for converting a measured aberration frequency into an estimate of absorbed dose (also appears as “dose”);

h) the reporting of results;

i) the QA and QC;

j) Annexes A to F containing sample instructions for the customer, sample questionnaire, sample datasheet for recording aberrations, sample of report and fitting of the low dose-response curve by the method of maximum likelihood and calculating the uncertainty of dose estimate.

2 Normative references

There are no normative references in this document.