



NSAI
Standards

Irish Standard
I.S. EN ISO 20046:2021

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

I.S. EN ISO 20046:2021

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National Foreword

I.S. EN ISO 20046:2021 is the adopted Irish version of the European Document EN ISO 20046:2021, Radiological protection - Performance criteria for laboratories using Fluorescence In Situ Hybridization (FISH) translocation assay for assessment of exposure to ionizing radiation (ISO 20046:2019)

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EUROPEAN STANDARD

EN ISO 20046

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EUROPÄISCHE NORM

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

EN ISO 20046:2021 (E)

Contents	Page
European foreword.....	3

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of an identical text or by endorsement, at the latest by August 2021, and conflicting national standards shall be withdrawn at the latest by August 2021.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

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INTERNATIONAL STANDARD

ISO
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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



Reference number
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Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Translocation assay by FISH	5
4.1 General.....	5
4.2 Culturing and fixation.....	5
4.3 Types of staining.....	5
4.4 Scoring.....	6
4.5 General requirement of the laboratory.....	6
5 Responsibility of the customer	6
6 Responsibility of the laboratory	7
6.1 Setup and sustainment of the QA program.....	7
6.2 Responsibility during service.....	7
7 Confidentiality of personal information	8
7.1 Overview.....	8
7.2 Applications of the principle of confidentiality.....	8
7.2.1 Delegation of responsibilities within the laboratory.....	8
7.2.2 Requests for analysis.....	9
7.2.3 Transmission of confidential information.....	9
7.2.4 Anonymity of samples.....	9
7.2.5 Reporting of results.....	9
7.2.6 Storage of data and results.....	9
8 Laboratory safety requirements	9
8.1 Overview.....	9
8.2 Microbiological safety requirements.....	10
8.3 Chemical safety requirements.....	10
8.4 Optical safety requirements.....	11
8.5 Safety plan.....	11
9 Sample processing	11
9.1 Culturing and staining.....	11
9.2 Scoring.....	12
9.2.1 Criteria for scoring.....	12
9.2.2 Conversion of translocation frequencies to genome equivalence.....	12
10 Background levels of translocations	13
11 Calibration curves	14
11.1 Calibration source(s).....	14
11.2 Establishment of calibration curve(s).....	14
12 Criteria for converting a measured aberration frequency into an estimate of absorbed dose	16
12.1 Determination of estimated whole-body absorbed dose and confidence limits.....	16
12.1.1 General.....	16
12.1.2 Comparison with the background level: Characterisation of the minimum detectable dose.....	16
12.1.3 Confidence limits on the number of translocations.....	19
12.1.4 Adjustment for background yield.....	20
12.1.5 Calculation of absorbed dose.....	21
12.1.6 Calculation of uncertainty on absorbed dose.....	22

ISO 20046:2019(E)

	12.1.7 Acute and non-acute exposure cases.....	22
	12.1.8 Other exposure scenarios	23
13	Reporting of results.....	23
	13.1 General.....	23
	13.2 Content of the report (see Annex C for an example of a standard form).....	23
	13.3 Interpretation of the results.....	24
14	Quality assurance and quality control.....	24
	14.1 Overview	24
	14.2 Specific requirements	24
	14.2.1 General.....	24
	14.2.2 Performance checks by inter-laboratory comparisons	24
	14.2.3 Performance check of scorer qualification.....	25
	14.2.4 Performance checks of sample transport integrity	25
	14.2.5 Performance checks of sample integrity by service laboratory.....	26
	14.2.6 Performance checks of instrumentation.....	26
	14.2.7 Performance checks of sample protocol	26
	14.2.8 Performance checks of sample scoring.....	26
	14.2.9 Performance checks of result report generation	26
	Annex A (informative) Sample instructions for customer.....	27
	Annex B (informative) Sample questionnaire	29
	Annex C (informative) Sample of report.....	31
	Annex D (informative) Sample data sheets for recording painted aberrations.....	32
	Annex E (informative) Fitting of the dose response-curve by the method of maximum likelihood and calculating the uncertainty of the absorbed dose estimate.....	34
	Annex F (informative) Process for dose estimation.....	35
	Bibliography.....	40

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 (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.

ISO 20046:2019(E)

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.

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.

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>
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