ICS 13.280 SLOVENSKÁ TECHNICKÁ NORMA Október 2024

STN	**Radiačná ochrana Kritériá spôsobilosti laboratórií používajúcich pri biologickej dozimetrii cytokinetickú blokovú mikronukleovú skúšku (CBMN) v periférnych krvných lymfocytoch (ISO 17099: 2024)**	**STN EN ISO 17099** 40 1406

Radiological protection - Performance criteria for laboratories using the cytokinesis-block micronucleus (CBMN) assay in peripheral blood lymphocytes for biological dosimetry (ISO 17099:2024)

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. 09/24

Obsahuje: EN ISO 17099:2024, ISO 17099:2024

Oznámením tejto normy sa ruší
STN EN ISO 17099 (40 1406) z marca 2018

139131

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17099

June 2024

ICS 13.280

Supersedes EN ISO 17099:2017

English Version

Radiological protection - Performance criteria for laboratories using the cytokinesis-block micronucleus (CBMN) assay in peripheral blood lymphocytes for biological dosimetry (ISO 17099:2024)

Radioprotection - Critères de performance pour les laboratoires pratiquant la dosimétrie biologique par l'analyse des micronoyaux par blocage de la cytodiérèse (CBMN) dans les lymphocytes du sang périphérique (ISO 17099:2024)

Strahlenschutz - Leistungskriterien für Laboratorien, die den Zytokineseblock-Mikronukleustest (CBMN) in peripheren Blutlymphozyten für die biologische Dosimetrie verwenden (ISO 17099:2024)

This European Standard was approved by CEN on 24 June 2024.

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

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Ref. No. EN ISO 17099:2024 E

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European foreword

This document (EN ISO 17099:2024) 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of an identical text or by endorsement, at the latest by December 2024, and conflicting national standards shall be withdrawn at the latest by December 2024.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.

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Endorsement notice

The text of ISO 17099:2024 has been approved by CEN as EN ISO 17099:2024 without any modification.

International Standard

ISO 17099

Radiological protection — Performance criteria for laboratories using the cytokinesis-block micronucleus (CBMN) assay in peripheral blood lymphocytes for biological dosimetry

Radioprotection — Critères de performance pour les laboratoires pratiquant la dosimétrie biologique par l'analyse des micronoyaux par blocage de la cytodiérèse (CBMN) dans les lymphocytes du sang périphérique

Second edition
2024-06

Reference number
ISO 17099:2024(en)

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Published in Switzerland

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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 second edition cancels and replaces the first edition (ISO 17099:2014), which has been technically revised.

The main changes are as follows:

— minor edits to text throughout;

— reorganization of document to better harmonize with other biological dosimetry standards;

— addition of 7.2.7 on data security plan;

— additional requirements added for the report on the conditions of the exposure for the calibration curve in 10.2;

— relaxation of the number of individuals required for each age group for establishing background micronucleus frequency, leaving the determination up to the head of the laboratory (10.3);

— addition of details on determining the minimal resolvable dose (10.4), the absorbed dose (11.2.4) and the uncertainty (11.2.5);

— removal of reference to coefficient of variance when determining scoring expertise, focussing on the use of 95 % confidence intervals to determine expertise (11.1.3);

— addition of reference to other exposure scenarios (11.2.8);

— removal of Annex on automated micronuclei scoring as it was deemed outside of the scope of the standard;

— addition of a sample group report (see Annex E);

— addition of a detailed annex (see Annex F) for calculating the decision threshold and detection limit along with a sample calculation and R script for performing these calculations.

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 the cytokinesis-block micronucleus (CBMN) assay with human peripheral blood lymphocytes for biological dosimetry of exposure to ionizing radiation. This assay is intended to be applied for accidental or malevolent exposures involving

a) up to a few casualties to provide individual whole-body dose estimates, or

b) in a triage mode to populations to provide rapid, lower accuracy dose estimates for individuals that can be improved with more accurate analysis at a later time.

The CBMN assay is an alternative cytogenetic technique, which is possibly simpler and faster to perform than the dicentric assay[1][2]. It is also routinely used to demonstrate exposure to genotoxic agents, other than ionizing radiation, which is not covered in this document. Although culture of the blood samples is slightly longer than for dicentrics, the scoring of micronuclei (MN) in binucleated lymphocytes is easier.

As was done with the dicentric assay, the CBMN assay has been adapted for the emergency triage of large-scale multi-casualty nuclear or radiological incident. The blood volume required for a sufficient number of scorable binucleated cells (BNCs) is similar to that required for the dicentric assay. Again, the faster counting speed for MN compensates for the extended culture time. However, it has to be considered that factors such as age, sex, diet and environmental mutagens can have an influence on the results particularly after low dose exposures[3][4][5]. In addition, the CBMN assay can be performed in an automated mode using various cytometric technologies but these are outside the scope of this document.

This document provides a guideline on how to perform the CBMN assay for dose assessment using documented and validated procedures. Dose assessment using the CBMN assay has relevance in medical management, radiation-protection management, record keeping, and medical/legal requirements. This document is divided into two parts, according to the use of CBMN assay: radiation exposure of a few individuals or population triage in a large radiological or nuclear event.

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, the criteria of accreditation and the evaluation of performance. This document is generally in conformity with ISO/IEC 17025[6] with particular consideration given to the specific needs of biological dosimetry. The expression of uncertainties in dose estimations given in this document complies with ISO/IEC Guide 98-3[15] (former GUM) and the ISO 5725 (all parts)[7].

International Standard ISO 17099:2024(en)

Radiological protection — Performance criteria for laboratories using the cytokinesis-block micronucleus (CBMN) assay in peripheral blood lymphocytes for biological dosimetry

1 Scope

This document gives guidance on

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

b) laboratory safety requirements,

c) calibration sources and calibration dose ranges useful for establishing the reference dose-response curves that contribute to the dose estimation from CBMN assay yields and the detection limit,

d) performance of blood collection, culturing, harvesting, and sample preparation for CBMN assay scoring,

e) scoring criteria,

f) conversion of micronucleus frequency in BNCs into an estimate of absorbed dose,

g) reporting of results,

h) quality assurance and quality control, and

i) informative annexes containing sample instructions for customers, sample questionnaire, a microscope scoring data sheet, and a sample report.

This document excludes methods for automated scoring of CBMN.

2 Normative references

There are no normative references in this document.