SLOVENSKI STANDARD
SIST EN ISO 17099:2024

01-september-2024

Radiološka zaščita - Merila za delovanje laboratorijev, ki za biološko dozimetrijo uporabljajo analizo tvorjenja mikrojeder s citokinetskim blokom (CBMN) v perifernih krvnih limfocitih (ISO 17099:2024)

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

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

Ta slovenski standard je istoveten z: **EN ISO 17099:2024**

ICS:

13.280	Varstvo pred sevanjem	Radiation protection
71.040.10	Kemijski laboratoriji. Laboratorijska oprema	Chemical laboratories. Laboratory equipment

SIST EN ISO 17099:2024 **en,fr,de**

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

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

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

Contents

Page

European foreword **3**

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.

This document supersedes EN ISO 17099:2017.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

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)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword ..... **v**
Introduction ..... **vii**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 CMBN assay methodology used in this document **3**
4.1 General 3
4.2 Requests for analysis and blood sampling 3
5 Responsibility of the requestor **3**
6 Responsibility of the service laboratory **4**
6.1 Setup and sustainment of the quality assurance program 4
6.2 Responsibility during service 4
7 Confidentiality of personal information **5**
7.1 Overview 5
7.2 Applications of the principle of confidentiality 5
7.2.1 Delegation of responsibilities within the laboratory 5
7.2.2 Requests for analysis 6
7.2.3 Transmission of confidential information 6
7.2.4 Anonymity of samples 6
7.2.5 Reporting of results 6
7.2.6 Storage 6
7.2.7 Data security plan 6
8 Laboratory safety requirements **6**
8.1 Overview 6
8.2 Microbiological safety requirements 7
8.3 Chemical safety requirements 7
8.4 Optical safety requirements 8
8.5 Safety plan 8
9 Sample processing **8**
9.1 Culturing 8
9.2 Staining 10
9.3 Microscopy 10
9.4 Scoring of slides 10
9.4.1 General 10
9.4.2 Criteria for scoring 10
9.4.3 Scoring data sheets 11
9.5 Automated analysis 11
10 Calibration source(s), calibration curve, and minimum detectable dose **11**
10.1 Calibration source(s) 11
10.2 Calibration curve 11
10.3 Background MN frequency 12
10.4 Comparison with the background level: Characterisation of the minimum detectable dose 13
11 Accidental exposure involving few individuals **15**
11.1 Procedure for scoring MN in BNCs 15
11.1.1 Coding of samples and slides 15
11.1.2 Scoring techniques 16
11.1.3 Laboratory scoring expertise 16
11.2 Criteria for converting a MN yield into an estimate of absorbed dose 16
11.2.1 Overview 16

11.2.2 Comparison with controls ... 16
11.2.3 Confidence limits on the number of MN ... 16
11.2.4 Calculation of absorbed dose for whole-body exposures ... 16
11.2.5 Calculation of uncertainty on absorbed dose ... 17
11.2.6 Acute and non-acute exposure cases ... 17
11.2.7 Testing the distribution of MN per BNC ... 18
11.2.8 Other exposure scenarios ... 18
11.3 Reporting of results ... 18
11.3.1 General ... 18
11.3.2 Content of the report (see Annex D for a standard form) ... 18
11.3.3 Interpretation of the results ... 19

12 Population triage ... 19
12.1 General ... 19
12.2 Use of a CBMN assay network for large scale exposures ... 19
12.3 Procedure for scoring MN in BNCs ... 20
12.4 Criteria for converting a MN yield into an estimate of absorbed dose ... 20
12.5 Reporting of results ... 20

13 Quality assurance and quality control ... 20
13.1 Overview ... 20
13.2 Specific requirement ... 20
13.2.1 General ... 20
13.2.2 Performance checks by laboratory inter-comparisons ... 20
13.2.3 Periodical performance check of scorer qualification ... 21
13.2.4 Performance checks of sample transport integrity ... 21
13.2.5 Performance checks of sample integrity by service laboratory ... 21
13.2.6 Performance checks for instrumentation ... 21
13.2.7 Performance checks of sample protocol ... 22
13.2.8 Performance checks of sample scoring ... 22
13.2.9 Performance checks of dose and confidence limits estimation ... 22
13.2.10 Performance checks for result report generation ... 22

Annex A (informative) **Sample data sheet for recording MN in BNCs ... 23**

Annex B (informative) **Instructions for requestor (sample) ... 24**

Annex C (informative) **Sample questionnaire ... 25**

Annex D (informative) **Sample of report for single assessment ... 27**

Annex E (informative) **Sample group report ... 29**

Annex F (informative) **Decision threshold and detection limit ... 31**

Bibliography ... 34

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.