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Practice for blood irradiation dosimetry

Pratique de la dosimétrie pour l'irradiation du sang

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Explanatory Material

This international standard is part of the project between ISO and ASTM International to develop and maintain a group of ISO/ASTM dosimetry standards for radiation processing. In accordance with ISO/TC 85 N 1248, Maintenance Procedures for ISO/ASTM Radiation Processing Dosimetry Standards, a joint meeting of ISO/TC 85 WG3 Dosimetry for Radiation Processing and ASTM Committee E61 was held in New Orleans, Louisiana, on January 16-28 to review standards being considered for withdrawal, revision/amendment, or confirmation. Although ISO/ASTM 51939, published in 2005, had been reapproved in 2013, it was decided that this standard should be revised to bring it in line with the new format adopted for the ISO/ASTM standards. A review was conducted to determine if, in addition to the format changes, technical changes would be required. From this review it was decided that major changes should be made to the standard and that it should be revised as a major revision.

The new standard covers the irradiation of blood or blood components in self-contained blood irradiators using photons. The previous version also covered the use of teletherapy equipment and electron beams. The standard provides recommendations for properly implementing dosimetry in blood irradiation. The practice describes a means of achieving compliance with the requirments of ISO/ASTM Practice 52628 for dosimetry performed for blood irradiation and is intended to be read in conjunction with ISO/ASTM 52628.

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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.

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.

ASTM International is one of the world's largest voluntary standards development organizations with global participation from affected stakeholders. ASTM technical committees follow rigorous due process balloting procedures.

A project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this project, ASTM Commitee E61, Radiation Processing, is responsible for the development and maintenance of these dosimetry standards with unrestricted participation and input from appropriate ISO member bodies.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. Neither ISO nor ASTM International shall be held responsible for identifying any or all such patent rights.

International Standard ISO/ASTM 51939 was developed by ASTM Committee E61, Radiation Processing, through Subcommittee E61.04, Specialty Application, and by Technical Committee ISO/TC 85, Nuclear energy, nuclear technologies and radiological protection.

This fourth edition cancels and replaces the third edition (ISO/ASTM 51939:05(2013)), which has been technically revised.

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Standard Practice for Blood Irradiation Dosimetry[1]

This standard is issued under the fixed designation ISO/ASTM FDIS 51939; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

1. Scope

1.1 This practice outlines the irradiator installation qualification program and the dosimetric procedures to be followed during operational qualification and performance qualification of the irradiator. Procedures for the routine radiation processing of blood product (blood and blood components) are also given. If followed, these procedures will help ensure that blood product exposed to gamma radiation or X-radiation (bremsstrahlung) will receive absorbed doses with a specified range.

1.2 This practice covers dosimetry for the irradiation of blood product for self-contained irradiators (free-standing irradiators) utilizing radionuclides such as ^{137}Cs and ^{60}Co, or X-radiation (bremsstrahlung). The absorbed dose range for blood irradiation is typically 15 Gy to 50 Gy.

1.3 The photon energy range of X-radiation used for blood irradiation is typically from 40 keV to 300 keV.

1.4 This practice also covers the use of radiation-sensitive indicators for the visual and qualitative indication that the product has been irradiated (see ISO/ASTM Guide 51539).

1.5 This document is one of a set of standards that provides recommendations for properly implementing dosimetry in radiation processing and describes a means of achieving compliance with the requirements of ISO/ASTM Practice 52628 for dosimetry performed for blood irradiation. It is intended to be read in conjunction with ISO/ASTM Practice 52628.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and to determine the applicability or regulatory limitations prior to use.*

2. Referenced documents

2.1 *ASTM Standards:*[2]

E170 Terminology Relating to Radiation Measurements and Dosimetry

2.2 *ISO/ASTM Standards:*[2]

51026 Practice for Using the Fricke Dosimetry System

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51275 Practice for Use of a Radiochromic Film Dosimetry System

51310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System

51539 Guide for the Use of Radiation-Sensitive Indicators

51607 Practice for Use of the Alanine-EPR Dosimetry System

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

51956 Practice for Use of Thermoluminescence-Dosimetry Systems (TLD Systems) for Radiation Processing

52116 Practice for Dosimetry for a Self-Contained Dry-Storage Gamma-Ray Irradiator

52628 Practice for Dosimetry in Radiation Processing

52701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

2.3 *International Commission on Radiation Units and Measurements Reports (ICRU):*[3]

ICRU 80 Dosimetry Systems for Use in Radiation Processing

ICRU 85a Fundamental Quantities and Units for Ionizing Radiation

[1] This practice is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.04 on Specialty Application, and is also under the jurisdiction of ISO/TC 85/WG 3.

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[2] For referenced ASTM and ISO/ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from the International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814 U.S.A.

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2.4 *ISO Standards:*[4]

12749-4 Nuclear energy – Vocabulary – Part 4: Dosimetry for radiation processing

2.5 *ISO/IEC Standards:*[4]

17025 General Requirements for the Competence of Testing and Calibration Laboratories

2.6 *Guidelines on Blood Irradiation:*

Guidelines on the Use of Irradiated Blood Components (2013), Prepared by the BCSH Blood Transfusion Task Force[5]

Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products, (1993) US Food and Drug Administration[6]

Guidance for Industry, Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing (2000) US Food and Drug Administration[6]

2.7 *Joint Committee for Guides in Metrology (JCGM) Reports:*

JCGM 100:2008 GUM 1995, with minor corrections, Evaluation of measurement data – Guide to the expression of uncertainty in measurement[7]

JCGM 200:2012 (JCGM 200:2008 with minor revisions), VIM, International vocabulary of metrology – Basis and general concepts and associated terms[8]

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbed dose (D)*—quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to matter of mass dm (see ICRU 85a).

$$D = d\bar{\varepsilon}/dm \quad (1)$$

3.1.1.1 *Discussion*—The SI unit of absorbed dose is the gray (Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J/kg).

3.1.2 *absorbed-dose rate ($\dot{D}$)*—quotient of dD by dt, where dD is the increment of absorbed dose in the time interval dt, thus

$$\dot{D} = dD/dt \quad (2)$$

3.1.2.1 *Discussion*—The SI unit is $Gy \cdot s^{-1}$. However, the absorbed-dose rate is often specified in terms of its average value over longer time intervals, for example, in units of $Gy \cdot min^{-1}$ or $Gy \cdot h^{-1}$.

3.1.3 *absorbed-dose mapping*—measurement of absorbed dose within an irradiated product to produce a one, two, or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

3.1.3.1 *Discussion*—For a blood canister, such a dose map is obtained using dosimeters placed at specified locations within the canister.

3.1.4 *activity (A) (of an amount of radionuclide in a particular energy state at a given time)*—quotient of –dN by dt, where dN is the mean change in the number of nuclei in that energy state due to spontaneous nuclear transitions in the time interval dt (see ICRU 85a).

$$A = -dN/dt \quad (3)$$

Unit: s^{-1}

The special name for the unit of activity is the becquerel (Bq). 1 Bq = 1 s^{-1}.

3.1.4.1 *Discussion*—

(1) The former special unit of activity was the curie (Ci). 1 Ci = 3.7×10^{10} s^{-1} (exactly).

(2) The 'particular energy state' is the ground state of the nuclide unless otherwise specified.

(3) The activity of an amount of radionuclide in a particular energy state is equal to the product of the decay constant, λ, for that state and the number of nuclei in that state (that is, $A=N\lambda$).

3.1.5 *approved laboratory*—laboratory that is a recognized national metrology institute; or has been formally accredited to ISO/IEC 17025; or has a quality system consistent with the requirements of ISO/IEC 17025.

3.1.5.1 *Discussion*—A recognized national metrology institute or other calibration laboratory accredited to ISO/IEC 17025 should be used in order to ensure traceability to a national or international standard. A calibration certificate provided by a laboratory not having formal recognition or accreditation will not necessarily be proof of traceability to a national or international standard.

3.1.6 *bremsstrahlung*—broad-spectrum electromagnetic radiation emitted when an energetic charged particle is influenced by a strong electric or magnetic field, such as that in the vicinity of an atomic nucleus.

3.1.6.1 *Discussion*—

(1) In radiation processing, bremsstrahlung photons with sufficient energy to cause ionization are generated by the deceleration or deflection of energetic electrons in a target material. When an electron passes close to an atomic nucleus, the strong coulomb field causes the electron to deviate from its original motion. This interaction results in a loss of kinetic energy by the emission of electromagnetic radiation. Since such encounters are uncontrolled, they produce a continuous photon energy distribution that extends up to the maximum kinetic energy of the incident electron.

(2) The bremsstrahlung spectrum depends on the electron energy, the composition and thickness of the target, and the angle of emission with respect to the incident electron.

3.1.7 *calibration*—set of operations that establish under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

[4] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

[5] Available from the National Blood Transfusion Service, East Anglian Blood Transfusion Centre, Long Road, Cambridge, CB2 2PT United Kingdom.

[6] Available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Rockville, MD 20852-1488, USA.

[7] Document produced by working Group 1 of the Joint Committee for Guides in Metrology (JCGM WG1). Available free of charge at the BIPM website (http://www.bipm.org).

[8] Document produced by working Group 2 of the Joint Committee for Guides in Metrology (JCGM WG2). Available free of charge at the BIPM website (http://www.bipm.org).

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3.1.7.1 *Discussion*—Calibration conditions include environmental and irradiation conditions present during irradiation, storage and measurement of the dosimeters that are used for the generation of a calibration curve.

3.1.8 *dosimeter*—device that, when irradiated, exhibits a quantifiable change that can be related to absorbed dose in a given material using appropriate measurement instruments and procedures.

3.1.9 *dosimeter batch*—quantity of dosimeters made from a specific mass of material with uniform composition, fabricated in a single production run under controlled, consistent conditions and having a unique identification code.

3.1.10 *dosimetry system*—system used for measuring absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use.

3.1.11 *installation qualification (IQ)*—process of obtaining and documenting evidence that equipment has been provided and installed in accordance with specifications.

3.1.12 *irradiator turntable*—device used to rotate the sample during the irradiation process so as to improve dose uniformity.

3.1.12.1 *Discussion*—An irradiator turntable is often referred to as a turntable. Some irradiator geometries, for example with a circular array of radiation sources surrounding the product, may not need a turntable.

3.1.13 *isodose curves*—lines or surfaces of constant absorbed dose through a specified medium.

3.1.14 *measurement management system*—set of interrelated or interacting elements necessary to achieve metrological confirmation and continual control of measurement processes.

3.1.15 *operational qualification (OQ)*—process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

3.1.16 *performance qualification (PQ)*—process of obtaining and documenting evidence that the equipment as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product that meeting its specification.

3.1.17 *radiation-sensitive indicator*—material such as a coated or impregnated adhesive-backed substrate, ink, coating or other material which may be affixed to or printed on the product and which undergoes a visual change when exposed to ionizing radiation.

3.1.17.1 *Discussion*—Radiation-sensitive indicators are often referred to as "indicators."

3.1.18 *reference-standard dosimetry system*—dosimetry system, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.

3.1.19 *routine dosimetry system*—dosimetry system calibrated against a reference standard dosimetry system and used for routine absorbed-dose measurements, including dose mapping and process monitoring.

3.1.20 *simulated product*—material with radiation absorption and scattering properties similar to those of the product, material or substance to be irradiated.

3.1.20.1 *Discussion*—

(1) Simulated product is used during irradiator characterization as a substitute for the actual product, material or substance to be irradiated.

(2) When used in routine production runs in order to compensate for the absence of product, simulated product is sometimes referred to as compensating dummy.

(3) When used for absorbed-dose mapping, simulated product is sometimes referred to as phantom material.

3.1.21 *timer setting*—defined time interval during which product is exposed to radiation.

3.1.22 *transfer-standard dosimetry system*—dosimetry system used as an intermediary to calibrate other dosimetry systems.

3.1.23 *transit dose*—absorbed dose delivered to a product (or a dosimeter) while it travels between the non-irradiation position and the irradiation position, or in the case of a movable source while the source moves into and out of its irradiation position.

3.1.24 *validation*—documented procedure for obtaining, recording and interpreting the results to establish that a process will consistently yield product complying with predetermined specifications.

3.1.25 *X-radiation*—ionizing electromagnetic radiation which includes both bremsstrahlung and the characteristic radiation emitted when atomic electrons make transitions to more tightly bound states.

3.1.25.1 *Discussion*—In radiation processing applications (such as blood product irradiation), the principal X-radiation is bremmstrahlung.

3.1.26 *X-ray converter*—device for generating X-radiation (bremsstrahlung) from an electron beam, consisting of a target, means for cooling the target, and a supporting structure.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *blood product (blood and blood components)*—whole blood, red cells, frozen cells, platelet concentrates, apheresis platelets, granulocyte concentrates, and fresh or frozen plasma.

3.2.1.1 *Discussion*—Enclosure systems for blood and blood components are commonly referred to as "bags."

3.2.2 *canister*—container used to house the blood product or blood-equivalent product during the irradiation process.

3.3 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ISO 12749-4, ASTM Terminology E170, ICRU 85a and VIM; these documents, therefore, may be used as alternative references.

4. Significance and use

4.1 Blood and blood components are irradiated to predetermined absorbed doses to inactivate viable lymphocytes to help prevent transfusion-induced graft-versus-host disease (GVHD)

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