ISO/ASTM 51939

Third edition 2013-10-01

<text> Practice for blood irradiation dosimetry





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ISO/ASTM 51939:2005(Reapproved 2013)(E)

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 Subcommittee 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 third edition cancels and replaces the second edition (ISO/ASTM 51939:2005).



Standard Practice for Blood Irradiation Dosimetry¹

This standard is issued under the fixed designation ISO/ASTM 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 irradiator installation qualification, operational qualification, performance qualification, and routine product processing dosimetric procedures to be followed in the irradiation of blood and blood components by the blood-banking community. If followed, these procedures will help to ensure that the products processed with ionizing radiation from gamma, X-radiation (bremsstrahlung), or electron sources receive absorbed doses within a predetermined range.

1.2 This practice covers dosimetry for the irradiation of blood for these types of irradiators: self-contained irradiators (free-standing irradiators) utilizing ¹³⁷Cs, ⁶⁰Co or X-radiation (bremsstrahlung), teletherapy units, and electron accelerators. The absorbed dose range for blood irradiation is typically 15 Gy to 50 Gy. In some jurisdictions, the absorbed dose range for blood irradiation is 25 Gy to 50 Gy.

1.3 The energy range is typically from approximately 40 keV to 5 MeV for photons, and up to 10 MeV for electrons.

1.4 This practice also covers the use of radiation-sensitive indicators for the visual and qualitative indication that the product has been irradiated.

1.5 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
- E 170 Terminology Relating to Radiation Measurements and Dosimetry
- E 1026 Practice for Using the Fricke Reference Standard Dosimetry System
- E 2304 Practice for Use of a LiF Photo-Fluorescent Film Dosimetry System
- 2.2 ISO/ASTM Standards:²
- 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
- 51400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory
- 51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System
- 51539 Guide for the Use of Radiation-Sensitive Indicators
- 51607 Practice for Use of the Alanine-EPR Dosimetry System
- 51608 Practice for Dosimetry in an X-ray (Bremsstrahlung) Facility for Radiation Processing
- 51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing
- 51956 Practice for Thermoluminescent Dosimetry (TLD) for Radiation Processing
- 52116 Practice for Dosimetry for a Self-Contained Dry-Storage Gamma-Ray Irradiator

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

- ICRU 85 Fundamental Quantities and Units for Ionizing Radiation
- 2.4 Guidelines on Blood Irradiation:
- Guidelines on Gamma Irradiation of Blood Components for the Prevention of Transfusion-associated Graft-versushost Disease, Prepared by the BCSH Blood Transfusion Task Force⁴
- Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products, (1993) US Food and Drug Administration⁵
- Guidance for Industry, Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing (2000) US Food and Drug Administration⁵

3. Terminology

3.1 Definitions:

3.1.1 *absorbed dose* (*D*)—quantity of ionizing radiation energy imparted per unit mass of a specified material. 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). The mathematical relationship is the quotient of $d\epsilon$ by dm, where $d\epsilon$ is the mean

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.

⁴ Available from the National Blood Transfusion Service, East Anglian Blood Transfusion Centre, Long Road, Cambridge, CB2 2PT United Kingdom.

⁵ Available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Rockville, MD 20852-1488, USA.