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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.

Contents

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.

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.

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).

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)

in certain immunocompromised patients and those receiving related-donor products (**1**, **2**).[9]

4.2 The assurance that blood and blood components have been properly irradiated is of crucial importance for patient health. This shall be demonstrated by means of accurate absorbed-dose measurements on the product, or in simulated product.

4.3 Blood and blood components are usually irradiated using gamma radiation from ^{137}Cs or ^{60}Co sources, or X-radiation from X-ray units.

4.4 Blood irradiation specifications include a lower limit of absorbed dose, and may include an upper limit or central target dose. For a given application, any of these values may be prescribed by regulations that have been established on the basis of available scientific data (see 2.6).

4.5 For each blood irradiator, an absorbed-dose rate at a reference position within the canister is measured as part of irradiator acceptance testing using a reference-standard dosimetry system. That reference-standard measurement is used to establish operating parameters so as to deliver specified dose to blood and blood components.

4.6 Absorbed-dose measurements are performed within the blood or blood-equivalent volume for determining the absorbed-dose distribution. Such measurements are often performed using simulated product (for example, polystyrene is considered blood equivalent for ^{137}Cs photon energies).

4.7 Dosimetry is part of a measurement management system that is applied to ensure that the radiation process meets predetermined specifications (see ISO/ASTM Practice 52628).

4.8 Blood and blood components are usually irradiated in chilled or frozen condition. Care should be taken, therefore, to ensure that the dosimeters and radiation-sensitive indicators can be used under such temperature conditions.

4.9 Proper documentation and record keeping are critical components of a radiation process. Documentation and record keeping requirements may be specified by regulatory authorities or may be given in the corporation's quality policy.

4.10 Response of most dosimeters has significant energy dependence at photon energies of less than 100 keV, so proper care must be exercised when measuring absorbed dose in that energy range.

5. Type of irradiators and modes of operation

5.1 Self-contained irradiators expose samples to gamma irradiation produced by isotopes of either ^{137}Cs or ^{60}Co (**3**) (ISO/ASTM Practice 52116), or to low energy X-radiation (bremsstrahlung) produced by an X-ray tube. These irradiators house their radiation source in a protective lead shield or other appropriate high atomic number material in accordance with the safety requirements. Currently available units using low-energy X-radiation (bremsstrahlung) require less shielding than units containing gamma-emitting radioactive isotopes. Such units containing radionuclides usually have a mechanism to move the canister from the load/unload position to the irradiation position.

5.1.1 Some common methods used for improving absorbed-dose uniformity in the blood product are to either rotate the canister holding the blood product in front of the radiation source or to have multiple sources irradiating the product from different directions.

6. Radiation source characteristics

6.1 *Gamma Irradiators:*

6.1.1 The source of gamma radiation used in the irradiators considered in this practice consists of sealed ^{60}Co or ^{137}Cs radionuclides that are typically linear rods arranged in one or more planar or annular arrays.

6.1.2 Cobalt-60 emits photons with energies of approximately 1.17 and 1.33 MeV in nearly equal proportions. Cesium-137 produces photons with energies of approximately 0.662 MeV.

6.1.3 The radioactive decay half-lives for ^{60}Co and ^{137}Cs are regularly reviewed and updated. The most recent publication by the National Institute of Standards and Technology gave values of 1925.20 (±0.25) days for ^{60}Co and 11018.3 (±9.5) days for ^{137}Cs (**4**).

6.1.4 For gamma sources, the only variation in the source output is the known reduction in the activity caused by radioactive decay. This reduction in the source output and the required increase in the irradiation time to deliver the same dose may be calculated (see 10.4.2) or obtained from tables provided by the irradiator manufacturer.

6.2 *X-ray Irradiators,*

6.2.1 Low energy X-ray irradiators use X-ray tubes that consist of an electron source (generally a heated wire, a filament which emits electrons), an electrostatic field to accelerate these electrons, and a converter to generate X-radiation.

6.2.2 An X-ray (bremsstrahlung) irradiator emits short-wavelength electromagnetic radiation, which is analogous to gamma radiation from radioactive sources. Although their effects on irradiated materials are generally similar, these kinds of radiation differ in their energy spectra (see 6.2.3), angular distribution, and dose rates. The physical characteristics of the X-radiation (bremsstrahlung) field depend on the design of the X-ray tube.

6.2.3 Currently available low-energy X-ray irradiators generate X-radiation with a maximum energy of 160 keV. The spectrum of the X-ray energy extends from the maximum energy to approximately 30 keV.

6.2.4 The energy of the X-radiation influences the size and shape of the canister needed to achieve the desired level of dose uniformity in the blood canister. Filters are used to reduce the low-energy components to improve dose uniformity in the canister. These filters may form part of the X-ray tube or may be material added to the irradiator or canister. Reflectors may also be used to improve the dose uniformity.

6.2.5 The absorbed-dose rate and thus time of irradiation is determined by the tube current.

[9] The boldface numbers in parentheses refer to the bibliography at the end of this standard.

7. Dosimetry systems

7.1 *Description of Dosimeters and Dosimetry Systems*—Classification of dosimeters and dosimetry systems is based on the inherent metrological dosimeter properties and the field of application of the dosimetry system (see ISO/ASTM Practice 52628). These classifications influence both the selection and calibration of dosimetry systems.

7.1.1 *Classification of Dosimeters*—Classification of dosimeters is based on their inherent metrological properties. The method of measurement may be important in the classification, but the classification does not include consideration of the actual instrumentation used, or the quality of preparation (manufacturer) of the dosimeter.

7.1.1.1 *Type I Dosimeters*—In order for a dosimeter to be classified as a type I dosimeter, it must be possible to apply accurate, independent corrections to its response to account for the effects of influence quantities, such as temperature and dose rate. See ISO/ASTM Practice 52628 for a list of type I dosimeters.

7.1.1.2 *Type II Dosimeters*—The classification of a dosimeter as a type II dosimeter is based on the complexity of interaction between influence quantities, such as temperature and dose rate, which makes it impractical to apply independent correction factors to the dosimeter response. See ISO/ASTM Practice 52628 for a list of type II dosimeters.

7.1.2 *Classification of Dosimetry Systems:*

7.1.2.1 *Reference Standard Dosimetry Systems:*

(1) The classification of a dosimetry system as a reference standard dosimetry system is based on its application. Reference standard dosimetry systems are used as standards to calibrate other dosimetry systems that are used for routine measurements. In addition, the reference standard dosimetry systems are used to certify the absorbed-dose rate at a reference position within the irradiator. The uncertainty of the reference standard dosimetry system will affect the uncertainty of the system being calibrated and thus the uncertainty in the absorbed dose value for the product being irradiated.

(2) Reference standard dosimetry systems may take the form of systems held at a given location or they may take the form of transfer standard dosimetry systems operated by a national standards laboratory or an approved laboratory. In the case of transfer standard dosimetry systems, dosimeters are sent to a blood irradiation facility for irradiation and then returned to the issuing laboratory for measurement. The requirement that dosimeters be transported without unduly increasing the measurement uncertainty restricts the type of dosimeter that can be used. Alanine/EPR and Fricke dosimetry systems are commonly used in this way.

(3) The dosimeter used in a reference standard dosimetry system is generally a type I dosimeter. The expanded uncertainty achievable with measurements made using a reference standard dosimetry system is typically of the order of 3 % (at the 95 % confidence level).

(4) Examples of reference standard dosimetry systems are given in Table 1.

7.1.2.2 *Routine Dosimetry Systems:*

(1) The classification of a dosimetry system as a routine dosimetry system is based on its application, that is, routine absorbed-dose measurements, including dose mapping and process monitoring.

(2) The dosimeter used in a routine dosimetry system is generally a type II dosimeter, although there may be exceptions, for example the use of type I alanine dosimeters. The expanded uncertainty achievable with measurements made using a routine dosimetry system is typically of the order of 6 % (at the 95 % confidence level).

(3) Examples of routine dosimetry systems are listed in Table 2 and described in more detail in Annex A1.

7.2 *Routine Dosimetry System Calibration:*

7.2.1 Dosimetry systems consist of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use. Prior to use, routine dosimetry systems shall be calibrated in accordance with documented procedures that specify details of the calibration process. The calibration curve shall cover the dose range of 15 to 50 Gy, suitable for blood irradiation. All dosimetry equipment requires either calibration traceable to appropriate standards or performance checks to verify its operation (for more information, see the specific ISO/ASTM standard for the dosimetry system being used). Similarly, the dosimetry system shall be calibrated for each dosimeter batch used on the blood irradiator. If required by regulation or policy, it is necessary to demonstrate that dose measurements are traceable to recognized national or international standards.

7.2.2 Irradiation of calibration dosimeters is a critical component of the calibration of the dosimetry system. These shall be irradiated at the reference position in the canister where the dose rate was determined using reference or transfer standard dosimeters issued and analyzed by an approved laboratory. For gamma irradiators, the most commonly used transfer standard dosimetry systems for this purpose are either Fricke or alanine-EPR. For low-energy X-ray irradiators, ionization chambers or the alanine-EPR dosimetry system may be used as transfer standard dosimetry systems as long as they are calibrated for the appropriate energy (**5**, **8**).

7.2.3 Alternately, the dosimeters may be calibrated in accordance with ISO/ASTM Practice 51261.

TABLE 1 Examples of reference-standard dosimetry systems

Dosimeter	Readout System	Useful Absorbed-dose Range (Gy)	Reference
Alanine	EPR spectrometer	1 to 10^5	ISO/ASTM 51607
Fricke	UV spectrophotometer	20 to 400	ISO/ASTM 51026
Ionization chamber	Electrometer	Can be easily applied to the blood-irradiation dose range	(**5**)

TABLE 2 Examples of routine dosimetry systems

Dosimeter	Readout System	Useful Absorbed-dose Range (Gy)	Reference
TLD (for example, LiF)	Thermoluminescence reader	10^{-4} to 10^{3}	ISO/ASTM 51956
MOSFET semiconductor	Electronic reader	1 to 200	(6, 7)
RadioChromic film	UV/visible spectrophotometer, Transmission/Reflectance densitometer	10 to 10^{5}	ISO/ASTM 51275
Alanine	EPR Spectrometer	1 to 10^{5}	ISO/ASTM 51607
Radiochromic optical waveguide	Photometric means using dual wavelength photometry	1 to 10^{4}	ISO/ASTM 51310
Ionization chamber	Electrometer	Can be easily applied to the blood-irradiation dose range	(5)

7.2.4 Calibration of the routine dosimetry system shall be repeated at regular intervals to ensure that the accuracy of the absorbed-dose measurement is maintained within required limits.

7.3 *Dosimetry Applications*—There are several applications of dosimetry systems where blood is irradiated. These may include:

7.3.1 reference or transfer standard dosimetry system is used to determine the reference absorbed-dose rate in the canister (see 9.3.1 for more details).

7.3.2 routine dosimetry system is used for establishing absorbed-dose distribution (mapping) in the canister (see 9.3.2 for more details), and

7.3.3 routine dosimetry system is used to monitor the routine radiation process (see 10.3.3 and 11.2 for more details).

7.4 *Factors That Affect the Response of Dosimeters:*

7.4.1 Factors that affect the response of dosimeters (generally referred to as "influence quantities"), including environmental conditions and variations of such conditions within the irradiator, shall be known and their effect taken into account (see ISO/ASTM Practices 52628 and 52701 and the Standard of the specific dosimetry system).

7.4.2 The possible photon energy range for blood irradiation applications is from 40 keV to 1.33 MeV. Since response of many routine dosimeters depends on the photon energy, care must be taken to calibrate the dosimetry system for appropriate energy ranges.

8. Installation qualification

8.1 *Objective*—The purpose of an installation qualification program is to obtain and document evidence that the irradiator and measurement instruments have been delivered and installed in accordance with their specifications. Installation qualification includes documentation of the irradiator equipment and measurement instruments; establishment of testing, operation and calibration procedures for their use; and verification that the installed irradiator equipment and measurement instruments operate according to specification.

NOTE 1—Table A2.1 gives some recommended steps in the following areas: installation qualification, operational qualification, performance qualification, and routine product processing. The recommended steps in Table A2.1 are not meant to be exhaustive.

8.2 *Equipment Documentation*—Establish and document an installation qualification program that includes descriptions of the instrumentation and equipment and measurement instruments installed at the blood irradiation facility. This documentation shall be retained for the life of the irradiator. At a minimum, it shall include:

8.2.1 A description of the irradiator's specifications, characteristics and parameters, including any modifications made during or after installation,

8.2.2 A description of the location of the irradiator within the operator's premises, including its relation to any means provided for segregating unirradiated from irradiated products,

8.2.3 Operating instructions and standard operating procedures for the irradiator and associated measurement instruments,

8.2.4 Description of the construction and operation of the product handling system,

8.2.5 Licensing and safety documents and procedures, including those required by regulatory and occupational health and safety agencies,

8.2.6 A description of a calibration program to ensure that all processing equipment that may influence absorbed-dose delivery is calibrated periodically (for example, the reset timer mechanism on a gamma irradiator), and

8.2.7 Descriptions, operating procedures, and calibration procedures for associated measurement instruments or systems (such as those used for dosimetry).

8.3 *Equipment Testing and Calibration*—Test all processing equipment and instrumentation that may influence absorbed dose in order to verify satisfactory operation of the irradiator within the design specifications.

8.3.1 Implement a documented calibration program to ensure that all processing equipment and instrumentation that may influence absorbed-dose delivery are calibrated periodically.

8.3.2 If any modification or change is made to the irradiator equipment or measurement instruments during the installation qualification phase, they shall be re-tested.

9. Operational qualification

9.1 *Objective*—The purpose of operational qualification of an irradiator is to establish baseline data for evaluating irradiator effectiveness, predictability, and reproducibility for the range of conditions of operation for key processing parameters that affect absorbed dose in the blood product. As part of this process, dosimetry may be performed to: *(1)* establish relationships between the absorbed dose for a reproducible geometry and the operating parameters of the irradiator, *(2)* measure absorbed-dose in blood-equivalent material or other reference materials, and *(3)* measure the

absorbed-dose rate at a reference position within the canister filled with blood or simulated product.

9.1.1 In some cases, operational qualification may begin prior to the shipment of the irradiator to the customer's site. As part of release-for-shipment criteria, the irradiator manufacturer may perform absorbed-dose mapping to establish baseline data. After the unit is installed at the user's site, operational qualification is performed as part of the user's quality assurance plan (see ISO/ASTM Practice 52116).

9.2 *Dosimetry Systems*—Calibrate the routine dosimetry system as discussed in 7.2.

9.3 *Irradiator Characterization*—The absorbed dose received by any portion of blood product depends on the irradiator parameters (such as the source activity at the time of irradiation, the geometry of the source, the source-to-product distance and the irradiation geometry) and the process parameters (such as the irradiation time, the product composition and density and the product loading configuration within the canister).

9.3.1 *Absorbed-Dose Rate*—A reference- or transfer-standard dosimetry system, traceable to nationally or internationally recognized standards, shall be used to measure the absorbed-dose rate within blood product or simulated product at a reference position (such as the center of the product or simulated product volume) when the simulated product nearly completely fills the irradiation volume. The absorbed-dose rate at the reference position shall have a reproducible and documented relationship to the absorbed-dose rate at locations of maximum (D_{max}) and minimum (D_{min}) dose within the product or simulated product volume. This measurement of absorbed-dose rate at a reference position shall be used to establish the operating parameters (such as timer setting) necessary to deliver the specified absorbed-dose range.

NOTE 2—If the irradiation conditions are different than those during reference dose rate measurements, these results may not apply.

9.3.1.1 Most manufacturers of blood irradiators use a reference-standard dosimetry system to measure absorbed-dose rate at a reference position within simulated product following installation of (or, in the case of some units, before shipping) the irradiator.

NOTE 3—For reference standard dosimetry, the absorbed dose and absorbed-dose rate are expressed as absorbed dose and absorbed-dose rate to water.

9.3.1.2 Measurement of absorbed-dose rate at a reference position should be repeated periodically (for example, annually) and following any changes to the source, irradiation geometry, or other irradiator parameters that could affect absorbed-dose rate.

NOTE 4—To the degree possible, subsequent measurements of dose rate should be performed under similar conditions to allow direct comparison amongst test results. These results should agree with results of previous measurements, once source decay (if applicable) or other known factors that may affect dose are taken into account. Unexplained discrepancies that are beyond the limit of combined uncertainty for the two procedures should be investigated, as they could indicate problems with the dosimetry or the operation of the irradiator.

9.3.2 *Dose Mapping*—Ideally, the irradiation process is designed to irradiate blood uniformly throughout the irradiated volume; in reality, a certain variation in absorbed-dose through the product will exist. The irradiator characterization process includes mapping the absorbed-dose distributions for blood or simulated product, and identifying the magnitudes and locations D_{max} and D_{min} within the canister for a given set of operating parameters (for example, timer setting, product loading configuration).

9.3.2.1 Mapping of the absorbed-dose distribution shall be done by placing dosimeters throughout the actual or simulated product. Placement patterns should be used that can identify the locations of D_{max} and D_{min}. Typically, the blood product is relatively close to the radiation source, resulting in pronounced absorbed-dose gradients near the periphery of the blood or blood-component volume. It is important, therefore, to choose a dosimeter with adequate spatial resolution to detect these gradients. For more information on dose mapping, see 10.3.

NOTE 5—In the case of static irradiations (such as when the product is located at the center of an annular source array), the dose mapping should be done in three dimensions.

NOTE 6—Dosimetry data from previously characterized irradiators of the same design or theoretical calculations may provide useful information for determining the number and locations of dosimeter sets needed for this characterization process.

9.3.2.2 The dose mapping information may be provided as a table of dose values for specific locations or as isodose curves.

9.3.2.3 Changes in the product handling system (for example, irradiator turntable) or radiation source characteristics require a new absorbed-dose mapping.

9.3.3 *Transit Dose*—The transit dose and its relation to total absorbed dose should be considered.

9.3.3.1 Dosimetry performed at the same dose level as used for blood irradiation includes the transit dose contribution. Therefore, it is usually unnecessary to measure the transit dose separately.

10. Performance qualification

10.1 *Objective*—The purpose of performance qualification is to ensure that the absorbed-dose requirements for blood product can be satisfied by the selected irradiation procedure. Typically, the regulatory agency specifies the minimum and maximum absorbed dose for the process. Establishment of the process parameters to fulfill these absorbed-dose requirements is accomplished by absorbed-dose mapping (see 9.3.2) of the canister filled with blood product (or simulated product) in a specified loading configuration.

10.2 *Product Loading Configuration*—A loading configuration within the canisters for the irradiation shall be established for each blood product type. The documentation for this loading configuration shall include specifications for parameters that influence the absorbed-dose distribution. For irradiation of blood, these parameters could include volume of the blood product, and size and shape of the blood or blood component bag. The canister shall not be loaded beyond its designed maximum volume.

10.3 *Product or Simulated Product Absorbed-dose Mapping*—For blood product, there is a minimum dose to achieve the desired effect and a maximum dose that the blood can tolerate without unacceptable degradation in quality. Both

these limits are usually defined by the pertinent regulatory body. Establish the locations of the regions of D_{max} and D_{min} for the selected product-loading configuration from the dose-mapping data.

10.3.1 Results of absorbed-dose mapping are used to determine the degree of dose uniformity. In some cases, irradiator or process parameters can be adjusted to improve dose uniformity (for example, reducing the blood volume to exclude it from areas with low or high dose rates).

10.3.2 If any changes are made to the irradiation geometry or mode of operation that could affect the magnitude or location of the absorbed-dose extremes, repeat the absorbed-dose mapping to the extent necessary to establish the effect. In addition, the established dose rate should be verified.

10.3.3 *Routine Monitoring Position*—If routine monitoring during processing is required, identify a routine monitoring position for the selected loading configuration. This may be, for example, the location fo D_{min} or D_{max}, or an alternate location in or on the canister. Dosimeters or indicators should be placed at this position(s) during routine processing, so accessibility should be considered. During dose mapping, dosimeters shall be placed at this location so as to establish the relationship between dose at this location and D_{max} and D_{min}. This relationship shall be reproducible and documented as process control requirements.

10.4 *Establishing Operating Parameters*—To ensure that the absorbed dose is within specified limits, values of operating parameters shall be established for the selected product loading configuration, and dose specification. These values are established based on results of the absorbed-dose mapping described in 10.3 in conjunction with results of reference- or transfer-standard measurements of absorbed-dose rate at a reference position (see 9.3.1). For most gamma irradiation facilities, the absorbed dose is controlled by adjusting a single operating parameter such as the timer setting. The values that are established for the operating parameters should result in an absorbed-dose distribution that is within specified limits throughout the irradiation volume.

10.4.1 *Timer Setting Calculation*—The amount of time (t) required to deliver a desired dose D to the reference position is given by:

$$t = D/\mathrm{DR} \quad (4)$$

where DR is the current absorbed dose rate at that reference position.

10.4.2 *Adjusting for Radioactive Decay*—An important calculation in the use of gamma sources is the correction for radioactive decay. For a pure radionuclide source, the exponential loss of activity, A, with time is given by:

$$A_t = A_0 \cdot e^{-\lambda t} \quad (5)$$

where A_t is the source activity at time t, A_0 is the known activity at some earlier time (t=0), and λ is the decay constant for the given radionuclide.

10.4.2.1 Using the values of half-lives from 6.1.3, the values for λ for ^{60}Co and ^{137}Cs are:

$$\text{For } ^{60}\text{Co, } \lambda = 3.60039 \times 10^{-4}\ \text{day}^{-1} \quad (6)$$

$$\text{For } ^{137}\text{Cs, } \lambda = 6.29087 \times 10^{-5}\ \text{day}^{-1} \quad (7)$$

10.4.2.2 In practice, absorbed-dose rate can be substituted for activity in Eq 5. The absorbed-dose rate established during OQ or during a subsequent characterization of the irradiator with a reference or transfer standard dosimetry system (see 9.3.1) provides the value at t = 0. The absorbed-dose rate at t days later can be computed from Eq 5 using λ for the appropriate radionuclide from Eq 6 or Eq 7.

10.4.2.3 Typically, for irradiators with a ^{137}Cs radionuclide source, the timer setting is increased by approximately 1.1 % every six months to compensate for the loss of activity from the radioactive decay and to continue to deliver the dose within the specified limits. Typically, for irradiators with a ^{60}Co radionuclide source, the timer setting is increased by approximately 1.1 % every month.

11. Routine product processing

11.1 *Operating Parameters and Control*—Before routine irradiation of blood product, set the operating parameters as established during performance qualification (taking into account source decay, if necessary). All critical operating parameters that can affect the absorbed-dose distribution shall be controlled and monitored during routine processing. These parameters include: for gamma irradiators – product loading, timer setting, and turntable rotation, and for X-ray irradiators – product loading, tube voltage and current, and canister rotation, if applicable. Control, monitor, and document the operating parameters to help ensure that the product is processed in accordance with specifications. If the operating parameters deviate from prescribed processing limits, take appropriate actions.

11.2 *Routine Monitoring of the Radiation Process*—Routine measurements of absorbed dose to the blood product will help ensure that the product has been treated with the dose range prescribed for the process. The absorbed dose may be measured at a routine monitoring position (see 10.3.3). Radiation-sensitive indicators may be used to monitor the radiation process (see ISO/ASTM Guide 51539). In order to detect any anomalies during the course of the irradiation, more than one routine monitoring position may be used.

11.2.1 *Process Monitoring Using Dosimeters*—Routine process monitoring may be performed using a routine dosimetry system. Routine dosimetry is part of the verification process for establishing that the irradiation process is under control.

NOTE 7—The absorbed-dose distribution in the canister is already known from the most recent dose mapping. However, the use of a sufficient number of strategically placed dosimeters serves to confirm that the absorbed dose delivered is within specification. In the routine operation of a blood irradiator, absorbed-dose measurements made on the product at regular intervals provide the operator and regulatory authorities an independent quality control record for the process. When D_{min} has been set by the regulatory authorities, the ability to measure the absorbed dose with proper statistical control is a critical requisite of Good Manufacturing Practices (GMPs).

11.2.1.1 *Dosimeter Location(s)*—When used, place one or more dosimeters on the blood bag or blood component bag at predetermined locations of the D_{max} and D_{min} or at a routine monitoring position (see 10.3.3 and 11.2). Under predefined conditions of operation, the absorbed dose at the routine

monitoring position has a quantitative and reproducible relationship with D_{max} and D_{min} (see 10.3.3).

11.2.1.2 *Dosimeter Placement Frequency*—A sufficient number of bags should be selected on which to place dosimeter sets in order to verify that the absorbed dose received by the product falls within specified limits. The pertinent regulatory body may prescribe this frequency.

11.2.2 *Process Monitoring Using Radiation-sensitive Indicators*—Routine process monitoring may be performed using radiation-sensitive indicators in order to obtain a visual and qualitative indication that the product has been irradiated.

NOTE 8—Use of radiation-sensitive indicators is not a replacement for use of dosimeters. Indicators cannot measure dose, but only qualitatively indicate that the blood bag has been irradiated.

11.2.2.1 *Radiation-sensitive Indicator Location*—When used, place one or more indicators on the blood product at predetermined accessible location(s).

11.2.2.2 *Radiation-sensitive Indicator Placement Frequency*—A sufficient number of bags should be selected on which to place indicators in order to verify that the product has been exposed to ionizing radiation. This frequency may be prescribed by the pertinent regulatory body.

11.3 *Environmental Effects*—If there is a change in the environment (for example, temperature or humidity) of a dosimeter or radiation-sensitive indicator during the irradiation process or pre- or post-irradiation storage, the response of the dosimeter and indicator may be affected. If this occurs, correct the dosimeter response for any such effect, if possible. A radiation-sensitive indicator's response cannot be corrected for such conditions, and therefore, care should be taken when using the indicators in those conditions. Care must also be taken in handling and storage of dosimeters and indicators before and after irradiation (see ISO/ASTM Practice 52701 and Guide 51539, and practices for individual dosimetry systems listed in 2.2).

11.4 *Chilled or Frozen Blood and Blood Components*—Absorbed dose is not a function of blood product temperature during irradiation. The response of the dosimeter and radiation-sensitive indicator, however, may be a function of temperature. The dose-mapping information for simulated product (representing the actual product geometry) at ambient temperature can be applied to the chilled or frozen product. If performing routine dosimetry with chilled product, determine the temperature of the dosimeter during irradiation of chilled or frozen blood and blood components and apply the appropriate temperature correction if applicable.

11.5 *Partially Loaded Canisters*—Irradiations may be performed using less product than that used for the dose mapping carried out during PQ (see 10.3). For partially loaded canisters, the D_{max} received by the product may be greater than the D_{max} measured in the fully loaded canister. Care must be taken, therefore, to ensure that the maximum dose allowed by regulation (if applicable) is not exceeded during routine irradiation. Changes to the absorbed-dose distribution arising from partially loaded canisters may be minimized by the use of simulated product placed at the appropriate locations in the canister.

12. Maintenance of validation

12.1 Mechanical and electrical checks of the entire irradiator should be performed periodically to provide assurance that the irradiator is consistently operating within specifications. Also, irradiator absorbed-dose mapping should be typically carried out on an annual cycle and should be repeated when changes are made to the irradiator that might affect the dose distribution in the blood product.

13. Measurement uncertainty

13.1 All dose measurements need to be accompanied by an estimate of uncertainty. Appropriate procedures are recommended in ISO/ASTM Guide 51707 and ISO/ASTM Practice 51261 (see also GUM).

13.2 All components of measurement uncertainty should be included in the estimate, including those arising from calibration, dosimeter variability, instrument reproducibility, and the effect of influence quantities. A full quantitative analysis of components of uncertainty is referred to as an uncertainty budget, and is then often presented in the form of a table. Typically, the uncertainty budget will identify all significant components of uncertainty, together with their methods of estimation, statistical distributions, and magnitudes.

14. Keywords

14.1 absorbed dose; absorbed-dose mapping; blood; blood components; blood products; blood irradiation; bremsstrahlung; dosimeter; dosimetry system; gamma radiation; irradiator; ionizing radiation; measurement quality assurance plan; measurement uncertainty; radiation-sensitive indicators; reference-standard dosimeter; routine dosimeter; transfer-standard dosimeter; ICS 17.240; X-radiation

ANNEXES

(informative)

A1. CHARACTERISTICS OF SOME ROUTINE DOSIMETERS

A1.1 Thermoluminescence dosimeter (TLD) dosimetry system

A1.1 For more information on this dosimetry system, see ISO/ASTM Practice 51956.

Applicable dose range: 10^{-4} to 10^{3} Gy

Applicable dose rate range: 10^{-2} to 10^{10} Gy s^{-1}

Use: Electrons/Gamma radiation/ X-radiation (Bremsstrahlung)

Physical characteristics of TLD: After irradiation, when crystalline material is subjected to a carefully controlled heating program, the freed electrons and holes from traps recombine with the emission of characteristic light. Most commonly employed materials for TLD are LiF, CaF_2, $CaSO_4$, and $Li_2Bi_4O_7$. The dosimeter is small and the material is used in the form of powder, pellets, single crystals, or in sealed glass tubes or bulbs, or suspended in plastics.

Instrumentation characteristics: Heat cycling TL reader.

Environmental factors:

Temperature: Not generally sensitive; however, varies with material.

Humidity: Not generally sensitive; however, varies with material.

Ambient Light: Varies with material.

Time: TLDs generally fade after irradiation; readout time after irradiation must be controlled.

Energy dependence: Sensitive to variation in X-ray energy

A1.2 MOSFET dosimeter

A1.2 For more information on this dosimetry system, see Refs (**6**, **7**).

Applicable dose range: 1 to 200 Gy

Applicable dose rate range: $<10^{-2}$ to 10^{8} Gy s^{-1}

Use: Electrons/Gamma radiation (Bremsstrahlung)

Physical characteristics of dosimeter: These dosimeters consist of semiconductor chips whose electrical characteristics change permanently upon irradiation. The electrical effect is measured electronically and is linear with absorbed dose over the specified dose range. The dosimeter is small and comes in the form of a sealed transistor package with pins to make electrical contact for reading. The dosimeter stores the dose information.

Instrumentation characteristics: The instrument is an electronic meter that measures a change in voltage on the dosimeter and converts this directly to absorbed dose. A printer is usually used which prints absorbed dose as well as time and date information. Operation of reader requires no special skill.

Environmental factors:

Temperature: Not sensitive.

Humidity: Not sensitive.

Ambient light: Not sensitive.

Time: Dosimeter read-out may change with time after irradiation.

Energy dependence: Sensitive to variation in X-ray energy

A1.3 Radiochromic film dosimetry system

A1.3 For more information on this dosimetry system, see ISO/ASTM 51275 and ICRU 80.

Applicable dose range: 1 to 10^{5} Gy

Applicable dose rate range: $<10^{13}$ Gy s^{-1}

Use: Electrons/Gamma radiation/ X-radiation (Bremsstrahlung)

Physical characteristics: These dosimeters consist of dyes that change color upon irradiation. Film thicknesses vary from a few micrometers to about 1 mm.

Instrumentation characteristics: VIS/UV spectrophotometer (various wavelengths).

Environmental factors:

Temperature: This dosimeter has positive irradiation temperature dependence effect depending on film type, and should be protected from temperatures >60°C.

Humidity: Some are sensitive to humidity (may be sealed in water-tight plastic envelopes).

Ambient light: These dosimeters are sensitive to ambient light conditions, especially ambient light with wavelengths <370 nm.

Energy dependence: Sensitive to variation in X-ray energy

A1.4 Alanine/EPR dosimetry system

A1.4 For more information on this dosimetry system, see ISO/ASTM Practice 51607 and ICRU 80.

Applicable dose range: 1 to 10^{5} Gy

Applicable dose rate range: $<10^{8}$ Gy s^{-1}

Use: Electrons/Gamma radiation/ X-radiation (Bremsstrahlung)

Physical characteristics: This dosimeter is used in the form of tablets, small rods, or rope of 3 to 5-mm diameter and various lengths, consisting primarily of α-alanine and a small amount of paraffin or other binder material.

Instrumentation characteristics: EPR spectrometer.

Environmental factors:

Temperature: Irradiation temperature coefficient varies with alanine formulation.

Humidity: Somewhat sensitive to humidity. May require preconditioning.

Ambient light: Not generally sensitive to UV light.

Energy dependence: Sensitive to variation in X-ray energy

A1.5 Radiochromic optical waveguide dosimetry system

A1.5 For more information on this dosimetry system, see ISO/ASTM Practice 51310.

Applicable dose range: 1 to 10^{4} Gy

Applicable dose rate range: < 10^{3} Gy s^{-1}

Use: Gamma radiation/ X-radiation (Bremsstrahlung)