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Practice for blood irradiation dosimetry

Pratique de la dosimétrie pour l'irradiation du sang

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Contents

Page

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 pilot project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this pilot project, ASTM Subcommittee E10.01, Dosimetry for 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 International Standard 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 E10, Nuclear Technology and Applications, through Subcommittee E10.01, and by Technical Committee ISO/TC 85, Nuclear Energy.

Annexes A1 and A2 of this International Standard are for information only.

Standard Practice for Blood Irradiation Dosimetry[1]

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 and dosimetric procedures to be followed in the irradiation of blood and blood products by the blood-banking community. If followed, these procedures will help to ensure that the products processed with ionizing radiation from gamma, bremsstrahlung X-rays 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 dry-storage ^{137}Cs or ^{60}Co irradiators (free-standing irradiators), teletherapy units, self-contained bremsstrahlung X-ray units and electron accelerators. The absorbed dose range for blood irradiation is typically 15 Gy to 50 Gy.

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

1.4 This practice is intended for use by technically and non-technically oriented people. It, therefore, contains more tutorial information than many other ASTM and ISO/ASTM dosimetry standards.

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:*

E 170 Terminology Relating to Radiation Measurements and Dosimetry[2]

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods[3,4]

E 456 Terminology Relating to Quality and Statistics[3,4]

E 666 Practice for Calculating Absorbed Dose from Gamma or X Radiation[2]

E 668 Practice for Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation-Hardness Testing of Electronic Devices[2]

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System[2]

2.2 *ISO/ASTM Standards:*

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing[2]

51275 Practice for Use of a Radiochromic Film Dosimetry System[2]

51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System[2]

51539 Guide for the Use of Radiation-Sensitive Indicators[2]

51540 Practice for Use of a Radiochromic Liquid Dosimetry System[2]

51607 Practice for Use of the Alanine-EPR Dosimetry System[2]

51608 Practice for Dosimetry in an X-ray (Bremsstrahlung) Facility for Radiation Processing[2]

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing[2]

2.3 *National Council on Radiation Protection and Measurements (NCRP) Publications*[5]

NCRP Report No. 58, A Handbook of Radioactivity Measurement Procedures, 1985.

NCRP Report No. 69, Dosimetry of X-ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV, December 1981.

2.4 *International Commission on Radiation Units and Measurements Reports (ICRU)*[6]

ICRU 14 Radiation Dosimetry: X-rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV

ICRU 17 Radiation Dosimetry: X-rays Generated at Potentials of 5 to 150 kV

ICRU 30 International Comparison of Radiological Units and Measurements Quantitative Concepts and Dosimetry in Radiobiology

ICRU 34 The Dosimetry of Pulsed Radiation

ICRU 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV

[1] This practice is under the jurisdiction of ASTM Committee E10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing, and is also under the jurisdiction of ISO/TC 85/WG 3.

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[2] *Annual Book of ASTM Standards*, Vol 12.02.

[3] *ASTM Standards on Precision and Bias for Various Applications*, 4th ed., 1992.

[4] *Annual Book of ASTM Standards*, Vol 14.02.

[5] Available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814 U.S.A.

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

ICRU 60 Radiation Quantities and Units

2.5 *Guidelines on Blood Irradiation*

Guidelines on Gamma Irradiation of Blood Components for the Prevention of Transfusion-associated Graft-versus-host Disease, Prepared by the BCSH Blood Transfusion Task Force.[7]

Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products. (1993) US Food and Drug Administration.[8]

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 $d\bar{\epsilon}$ by dm, where $d\bar{\epsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm (see ICRU 60).

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

3.1.1.1 *Discussion*—

1. The discontinued unit for absorbed dose is the rad (1 rad = 100 erg/g = 0.01 Gy).

2. Absorbed dose is sometimes referred to simply as dose.

3. For a photon source under conditions of charged particle equilibrium, the absorbed dose, D, may be expressed as follows:

$$D = \Phi[E(\mu_{en}/\rho)], \quad (2)$$

where:

Φ = particle fluence (particles/m ^{2}),

E = energy of the ionizing radiation (J), and

μ_{en}/ρ = mass energy absorption coefficient (m^2/kg).

4. If bremsstrahlung production within the specified material is negligible, the mass energy absorption coefficient (μ_{en}/ρ) is equal to the mass energy transfer coefficient (μ_{tr}/ρ), and absorbed dose is equal to kerma.

3.1.2 *absorbed-dose rate ($\dot{D}$)*—the absorbed dose in a material per incremental time interval, ie. the quotient of dD by dt.

$$\dot{D} = dD / dt \quad (3)$$

Unit: $Gy \cdot s^{-1}$.

3.1.2.1 *Discussion*—The absorbed-dose rate can be specified in terms of average value of D over long-time intervals, for example, in units of $Gy \cdot min^{-1}$ or $Gy \cdot h^{-1}$.

3.1.3 *blood product*—a unit of blood or specific blood component.

3.1.4 *canister*—a container, usually an aluminum or steel cylinder, used to house the blood product, or blood-equivalent product during the irradiation process.

3.1.5 *dose uniformity ratio*—ratio of maximum to minimum absorbed dose within the irradiated blood or blood product. This concept is also referred to as the "max/min ratio."

3.1.5.1 *Discussion*—The central plane/minimum ratio is not used in this standard.

3.1.6 *dosimeter*—a device that, when irradiated, exhibits a quantifiable change in some property of the device which can be related to absorbed dose in a given material using appropriate analytical instrumentation and techniques.

3.1.6.1 *Discussion*—A dosimeter must exhibit the reproducible and quantifiable properties that allow it to be calibrated and compared to national standards.

3.1.7 *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.

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

3.1.9 *irradiator turntable*—device used to rotate the canister during the irradiation process to improve the dose uniformity ratio.

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

3.1.10 *measurement quality assurance plan*—A documented program for the measurement process that ensures on a continuing basis that the overall uncertainty meets the requirements of the specific application. This plan requires traceability to, and consistency with, nationally- or internationally-recognized standards.

3.1.11 *radiation-sensitive indicator*—a material such as coated or impregnated adhesive-back substrates, inks, or coatings which may be affixed to or printed on the blood product or blood component product and which undergo a visual change when exposed to ionizing radiation (see ISO/ASTM Guide 51539).

3.1.11.1 *Discussion*—Radiation-sensitive indicators are often referred to as "indicators." Radiation-sensitive indicators cannot be classified as a "label" under the U.S. FDA "Guidelines for the Uniform Labeling of Blood and Blood Products" (August, 1985).[8] Indicators may be used to show that products have been exposed to ionizing radiation. They can be used to provide a visual and qualitative indication of radiation exposure and can be used to distinguish between irradiation-processed blood products and unprocessed blood products. Indicators cannot be used as a substitute for proper dosimetry.

3.1.12 *reference–standard dosimeter*—a dosimeter of high metrological quality, used as a standard to provide measurements traceable to and consistent with measurements made with primary–standard dosimeters (see ISO/ASTM Guide 51261).

3.1.13 *routine dosimeter*—dosimeter calibrated against a primary–, reference-, or transfer-standard dosimeter and used

[7] Available from the National Blood Transfusion Service, East Anglian Blood Transfusion Centre, Long Road, Cambridge, CB2 2PT United Kingdom, Tel (0223) 245921, Fax (0223) 411618.

[8] Available from the Office of Blood Research and Review, US Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, USA.

for routine absorbed-dose measurement (see ISO/ASTM Guide 51261).

3.1.14 *simulated product*—a mass of material with attenuation and scattering properties similar to those of the product, material or substance to be irradiated.

3.1.14.1 *Discussion*—Simulated product is used during irradiator characterization as a substitute for the actual product, material or substance to be irradiated. When used for absorbed-dose mapping, simulated product is sometimes referred to as a phantom material.

3.1.15 *transfer–standard dosimeter*—a dosimeter, often a reference–standard dosimeter, suitable for transport between different locations for use as an intermediary to compare absorbed-dose measurements (see ISO/ASTM Guide 51261).

3.1.16 *transit dose*—absorbed dose delivered to product while the product moves from the load/unload position to the irradiate position, and back to the load/unload position.

3.1.17 *validation*—establishment of documented evidence which provides a high degree of assurance that a specified process will consistently produce a product meeting its predetermined specifications and quality attributes.

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E 170. Definitions in ASTM E 170 are compatible with ICRU 60; that document, therefore, may be used as an alternative reference.

4. Significance and Use

4.1 Blood products include whole blood, red cells, frozen cells, platelet concentrates, apheresis platelets, granulocyte concentrates, and fresh (frozen) plasma. The assurance that blood or blood products have been properly irradiated is of crucial importance for patient health. The irradiator operator must demonstrate by means of accurate absorbed-dose measurements on the product, or in simulated product, that the specified absorbed dose has been achieved throughout the product.

4.2 Blood and various blood products are irradiated at pre-determined doses to inactivate viable lymphocytes to help prevent transfusion-induced graft-versus-host disease (GVHD) in selected immunocompromised patients and those receiving related-donor products **(1,2)**.[9]

4.3 Blood products may be treated with ionizing radiation, such as gamma rays from ^{137}Cs or ^{60}Co sources, and from self-contained bremsstrahlung X-ray units and medical linear X-ray and electron accelerators used primarily for radiotherapy.

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.

4.5 For each blood irradiator, an absorbed-dose rate at a reference dose position within the blood- or blood-equivalent volume is measured by the manufacturer as part of acceptance testing using a reference-standard dosimetry system. That reference-standard measurement must be used to calculate the timer setting required to deliver the specified absorbed dose to the center of the blood or blood component, or other reference position of the container filled with blood products. Either relative or absolute absorbed-dose measurements are performed within the blood- or blood-equivalent volume for determining the absorbed-dose distribution. Accurate radiation dosimetry at a reference position which could be the position of the maximum absorbed dose (Dmax) or minimum absorbed dose (Dmin) offers a quantitative, independent method to monitor the radiation process.

4.6 Dosimetry is part of a measurement quality assurance program that is applied to ensure that the radiation process meets predetermined specifications **(4)**.

4.7 Absorbed-dose mapping is often performed using simulated product.

4.8 Proper documentation and record keeping are critical components of radiation processing. This standard does not address this issue since minimum requirements must be set by the pertinent governing bodies.

5. Type of Facilities and Modes of Operation

5.1 *Self-Contained Blood Irradiators*. **(5)** The majority of blood components are irradiated by gamma rays from either ^{137}Cs or ^{60}Co self-contained dry storage irradiators. These devices house the radiation source in a protective lead shield (or other appropriate high atomic number material), and usually have a mechanism to rotate or lower the canister from the load/unload position to the irradiation position.

5.1.1 The most common method used to ensure a uniform absorbed-dose distribution in the blood product is to rotate the canister holding the blood product on an irradiator turntable in front of the radiation source.

5.1.2 A second method is to distribute the source in a circular array. The blood product is located at the center of the array, resulting in a relatively uniform absorbed-dose distribution. In this design, irradiator turntables would not normally be necessary.

5.2 *Teletherapy Equipment*. ^{60}Co equipment and linear accelerator teletherapy equipment (in electron or bremsstrahlung X-ray modes) are used primarily for the treatment of tumors. These units may also be used to irradiate blood products. In both types of equipment, radiation is emitted or generated and directed at the blood products placed beneath the collimator. The collimator is used to create a highly defined beam of radiation.

5.3 *Electron Accelerator (Electron and Bremsstrahlung X-ray modes)*. Accelerator-generated radiation is in the form of electrons or bremsstrahlung X-rays. Teletherapy accelerators can be used for this purpose.

5.3.1 For an electron accelerator, the two principal beam characteristics are the energy spectrum and the average beam current. The electron energy spectrum affects the variation of absorbed dose with depth in a given material, and the average beam current affects the absorbed-dose rate.

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

5.3.2 A bremsstrahlung X-ray accelerator emits short-wavelength electromagnetic radiation, similar in energy to gamma radiation. Although their effects on materials are generally similar, these kinds of radiation differ in their energy spectra, angular distributions, and absorbed-dose rates.

5.3.3 Some blood components are irradiated using a self-contained portable bremsstrahlung X-ray blood irradiator. The bremsstrahlung X-rays are produced in a conventional manner, but the unit is totally self-contained (free standing). Spectrum filtration is used to reduce the low energy component of the radiation, thus improving the dose uniformity ratio. In some cases, irradiator turntables are used.

6. Radiation Source Characteristics

6.1 The radiation source used in a facility considered in this practice consists of sealed elements of ^{60}Co or ^{137}Cs which are typically linear rods or "pencils" arranged in one or more planar or cylindrical arrays, bremsstrahlung X-rays, or electrons.

6.2 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 **(3)**.

6.3 The half-lives for ^{60}Co and ^{137}Cs are approximately 5.2708 years **(14)** and 30.07 years **(15, 16)**, respectively.

6.4 For gamma-ray sources, the only variation in the source output is the known reduction in the activity caused by radioactive decay. The reduction in the source strength and the required increase in the irradiation time may be calculated (see 9.4.6) or obtained from tables provided by the irradiator manufacturer.

6.5 Direct-action electron accelerators which employ dc or pulsed high-voltage generators typically produce electron energies up to 5 MeV. Indirect-action electron accelerators use microwave or very high frequency (vhf) ac power to produce electron energies typically from 5 MeV to 15 MeV.

6.6 The continuous energy spectrum of the X-rays (bremsstrahlung) ranges from approximately 35 keV up to the maximum energy of the electrons incident on the X-ray target (see ISO/ASTM Practice 51608).

6.7 Regulations in some countries limit the maximum electron energy to 10 MeV and photon energy to 5 MeV.

7. Dosimetry Systems

7.1 *Description of Dosimeter Classes*:

7.1.1 Dosimetry systems are used to measure absorbed dose. They consist of the dosimeters, measurement instruments and their associated reference standards, and procedures for the systems' use.

7.1.2 Dosimeters may be divided into four basic classes according to their accuracy and areas of application: primary standard, reference standard, transfer standard, and routine dosimeters. ISO/ASTM Guide 51261 provides detailed information about the selection of dosimetry systems for different applications.

7.1.2.1 Primary–Standard Dosimeters: Primary–standard dosimeters are established and maintained by national standards laboratories for calibration of radiation environments (fields) and other dosimeters. The two most commonly used primary–standard dosimeters are ionization chambers and calorimeters (see ISO/ASTM Guide 51261, ICRU Reports 14, 17, 34 and 35 and NCRP Report 69).

7.1.2.2 Reference–Standard Dosimeters: Reference–standard dosimeters are used to calibrate radiation environments and routine dosimeters. Reference–standard dosimeters may also be used as routine dosimeters. Examples of reference–standard dosimeters used in blood irradiation, along with their useful dose ranges are given in Table 1.

7.1.2.3 *Transfer–Standard Dosimeters:* Transfer–standard dosimeters are specially selected dosimeters used for transferring absorbed-dose information from an accredited or national standards laboratory to an irradiation facility in order to establish traceability for that facility. These dosimeters should be used under conditions that are carefully controlled by the issuing laboratory. Transfer–standard dosimeters may be selected from either reference–standard dosimeters or routine dosimeters and shall have performance characteristics that meet the requirements listed in a table in ISO/ASTM Guide 51261. Examples of transfer-standard dosimeters used in blood irradiation are given in Table 2.

7.1.2.4 *Routine Dosimeters:* Routine dosimeters may be used for quality control and process monitoring. Proper dosimetric techniques, including calibration, shall be employed to ensure that measurements are reliable and accurate. Examples of routine dosimeters used in blood irradiation, along with their useful dose ranges are given in Table 3.

7.2 *Dosimeter Applications:* In general, routine dosimeters are used to monitor the radiation process on a routine basis as an integral part of process control, and may be used to perform dose mapping to determine the absorbed-dose distribution throughout the product or simulated product. The absorbed-dose rate at a specific location, which will be used to determine the time interval for the irradiation (or the timer setting), must be determined using higher-quality primary-, reference-, or transfer-standard dosimeters.

7.2.1 *Timer Setting Calculations:* The reference-standard measurement must be used to calculate the timer setting required to deliver the specified absorbed dose to the center of the blood or blood component, or other reference position of the container filled with blood products. The reference–standard dosimeter most widely used is the ferrous sulfate (Fricke) aqueous solution (see ASTM Practice E 1026). Other reference–standard dosimeters include ionization chambers (see NCRP Report 69 and Ref **(13)**) and radiochromic solutions (see ISO/ASTM Practice 51540 and Ref **(6)**).

7.2.1.1 Precise and accurate absorbed-dose measurements are made in simulated product routine-processing conditions. The irradiation time to deliver the required absorbed dose can then be accurately determined.

NOTE 1—For reference standard dosimetry, the absorbed dose and absorbed-dose rate can be expressed in water or other material which has similar absorption properties to that of blood and simulated-blood products.

7.2.2 *Quality Control and Routine Monitoring*—Routine dosimeters may be used for quality control and routine

TABLE 1 Examples of Reference-Standard Dosimeters

Dosimeter	Readout System	Useful Absorbed-dose Range (Gy)	Reference
Alanine	EPR Spectrometer	1 to 10^5	ISO/ASTM 51607
Ethanol-Chlorobenzene solution	Spectrophotometer, color titration, high frequency conductivity	10 to 2×10^6	ISO/ASTM 51538
Fricke	UV Spectrophotometer	20 to 400	ASTM E 1026
Ionization Chamber	Electrometer	Can be easily applied to the Blood-irradiation Dose Range[A]	**(13)**
Radiochromic Dye Solution	Spectrophotometer	10 to 4×10^4	ISO/ASTM 51540

[A] In principle, an ion chamber can be used to make absolute absorbed–dose rate measurements at any dose rate. In the blood–irradiation dose-rate range (for example, 5 to 20 Gy/min), the ion chamber will perform satisfactorily if it has been calibrated within the applicable dose-rate range.

TABLE 2 Examples of Transfer-Standard Dosimeters

Dosimeter	Readout System	Useful Absorbed Dose Range (Gy)	Reference
Alanine	EPR Spectrometer	1 to 10^5	ISO/ASTM 51607
Ethanol-Chlorobenzene solution	Spectrophotometer, color titration, high frequency conductivity	10 to 2×10^6	ISO/ASTM 51538
Fricke	UV Spectrophotometer	20 to 400	ASTM E 1026
Radiochromic Dye Solution	Spectrophotometer	10 to 4×10^4	ISO/ASTM 51540

TABLE 3 Examples of Routine Dosimeters

Dosimeter	Readout System	Useful Absorbed Dose Range (Gy)	Reference
TLD (e.g. LiF)	Thermoluminescence reader	10^{-4} to 10^3	ASTM E 668
MOSFET semiconductor	Electronic reader	1 to 200	**(7, 8)**
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

monitoring. Proper dosimetric measurements shall be employed to ensure that the product receives the desired dose, and to identify unexpected changes in the process. Routine measurements of absorbed dose to the blood product will help ensure that the product has been treated with the minimum dose prescribed by the process. The absorbed dose may be measured at a reference-dose position (see 10.3.2). Accurate radiation dosimetry at a reference position, which could be the position of the maximum absorbed dose (Dmax) or minimum absorbed dose (Dmin) offers a quantitative, independent method to monitor the radiation process. In order to detect any anomalies during the course of the irradiation, more than one routine monitoring position may be necessary. Routine dosimeters shall not be used to calculate or change the timer setting required to deliver the specified absorbed dose to the product. For more information on routine monitoring, see Section 11.

NOTE 2—In the routine operation of a blood irradiator, absorbed-dose measurements made on the product at regular intervals provide the operator and regulatory authorities with an independent quality control record for the process. When Dmin has been set by the regulatory authorities, the ability to measure that absorbed dose with proper statistical control is a critical requisite of Good Manufacturing Practices (GMPs).

7.2.3 *Absorbed-dose Mapping*—Ideally, the radiation process is designed to irradiate the blood product uniformly; in reality, a certain variation in absorbed dose through the product will exist. Absorbed-dose mapping is used to determine the magnitude and locations of Dmax and Dmin for a given set of operating parameters (e.g. timer setting, product loading configuration). For self-contained dry storage irradiators, the blood product may be 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 which is small enough to detect these gradients. The routine dosimetry system may be used for relative or absolute absorbed-dose measurements or for mapping the absorbed-dose distribution in the blood-irradiation volume. For more information on dose mapping, see 10.3.

7.3 *Calibration of Dosimetry Systems*:

7.3.1 Prior to use, dosimetry systems shall be calibrated in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. This calibration procedure shall be repeated at regular intervals to ensure that the accuracy of the absorbed-dose measurement is maintained within required limits. Irradiation is a critical component of the calibration of the dosimetry system. Detailed calibration procedures are provided in ISO/ASTM Guide 51261.

7.3.2 *Calibration Irradiation of Reference or Transfer–Standard Dosimeters*—Calibration irradiations shall be performed by irradiating the reference or transfer–standard dosimeters using a calibration facility that provides an absorbed dose or an absorbed-dose rate having measurement traceability to nationally or internationally recognized standards.