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Practice for blood irradiation dosimetry

Pratique de la dosimétrie pour l'irradiation du sang

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

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

A project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this project, ASTM 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).

An American National Standard

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, 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 ^{137}Cs, ^{60}Co 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-versus-host Disease, Prepared by the BCSH Blood Transfusion Task Force[4]

Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products, (1993) US Food and Drug Administration[5]

Guidance for Industry, Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing (2000) US Food and Drug Administration[5]

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.

incremental energy imparted by ionizing radiation to matter of incremental mass dm (see ICRU 85).

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

3.1.1.1 *Discussion*—The discontinued unit for absorbed dose is the rad (1 rad = 100 erg/g = 0.01 Gy). Absorbed dose is sometimes referred to simply as dose.

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

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

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

3.1.3 *absorbed-dose mapping*—measurement of absorbed dose within product using dosimeters placed at specified locations to produce a one, two, or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

3.1.4 *activity (A) (of an amount of radioactive nuclide in a particular energy state at a given time)*—quotient of dN by dt, where dN is the expectation value of the number of spontaneous nuclear transitions from that energy state in the time interval dt (see ICRU 85).

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

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

3.1.5 *blood and blood components*—include whole blood, red cells, frozen cells, platelet concentrates, apheresis platelets, granulocyte concentrates, and fresh or frozen plasma.

3.1.5.1 *Discussion*—Enclosure systems for blood and blood components are commonly referred to as "bags." The volume of a typical blood bag is less than 0.5 L. Blood and blood components are often referred to as blood product.

3.1.6 *calibration*—set of operations under specified conditions, which establishes the relationship between values indicated by a measuring instrument or measuring system, and the corresponding values realised by standards traceable to a nationally or internationally recognized laboratory.

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

3.1.8 *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."

3.1.9 *dosimeter*—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.

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

3.1.10 *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.

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

3.1.12 *installation qualification (IQ)*—obtaining and documenting evidence that the irradiator, with all its associated equipment and instrumentation, has been provided and installed in accordance with specifications.

3.1.13 *instrument traceability*—ability to demonstrate that a measurement instrument has been calibrated at acceptable time intervals against a national or international standard or against a secondary standard that has been calibrated against a national or international standard.

3.1.14 *irradiator sample chamber*—accessible enclosed volume in which a sample or sample holder may be placed in the loading/unloading position of the irradiator (typically a gamma cell) prior to irradiation, and which can be transported by the sample positioning system to the irradiation position.

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

3.1.15.1 *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.

3.1.16 *isodose curve*—lines or surfaces of constant absorbed dose through a specified medium.

3.1.17 *measurement quality assurance plan*—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.

3.1.18 *measurement traceability*—ability to demonstrate by means of an unbroken chain of comparisons that a measurement is in agreement within acceptable limits of uncertainty with comparable nationally or internationally recognized standards.

3.1.19 *operational qualification (OQ)*—obtaining and documenting evidence that installed equipment and instrumentation operate within predetermined limits when used in accordance with its operational procedures.

3.1.20 *performance qualification (PQ)*—obtaining and documenting evidence that the equipment and instrumentation, as installed and operated in accordance with operational procedures, consistently perform according to predetermined criteria and thereby yield product that meets specifications.

3.1.21 *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.

3.1.21.1 *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).[5] 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 irradiated blood and blood components and non-irradiated blood and blood components. Indicators cannot be used as a substitute for proper dosimetry.

3.1.22 *reference-standard dosimeter*—dosimeter of high metrological quality used as a standard to provide measurements traceable to measurements made with primary-standard dosimeters.

3.1.23 *routine dosimeter*—dosimeter calibrated against a primary-, reference-, or transfer-standard dosimeter and used for routine absorbed-dose measurement.

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

3.1.24.1 *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 phantom material.

3.1.25 *transfer-standard dosimeter*—dosimeter, often a reference-standard dosimeter, suitable for transport between different locations, used to compare absorbed-dose measurements.

3.1.26 *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.

3.1.27 *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.

3.1.28 *X-radiation (bremsstrahlung)*—common name for the short-wavelength electromagnetic radiation. The term includes both broad-spectrum bremsstrahlung (emitted when an energetic electron is influenced by a strong electric or magnetic field, such as that in the vicinity of an atomic nucleus) and the characteristic monoenergetic radiation (emitted when atomic electrons make transitions to more tightly bound states).

3.1.29 *X-ray (bremsstrahlung) 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 other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E 170E 170. Definitions in ASTM Terminology E 170E 170 are compatible with ICRU 85; that document, therefore, may be used as an alternative reference.

4. Significance and use

4.1 The assurance that blood and blood components 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 blood components are irradiated at predetermined 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)**.[6]

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

4.3.1 The terms “gamma rays” and “gamma radiation” are used interchangeably, as are the terms “X-ray” and “X-radiation.”

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 2.4.

4.5 For each blood irradiator, an absorbed-dose rate at a reference position within the canister is measured by the manufacturer as part of acceptance testing using a reference-standard dosimetry system. That reference-standard measurement is used to calculate the timer setting required to deliver the specified absorbed dose to the center of the canister with blood and blood components, or other reference position. 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 (D_{max}) or minimum absorbed dose (D_{min}) 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 **(3)**.

4.7 Absorbed-dose mapping is often performed using simulated product (for example, polystyrene is considered blood equivalent for ^{137}Cs photon energies).

4.8 Blood and blood components are usually chilled or frozen. 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 radiation processing. This standard does not address this issue since the pertinent governing bodies set minimum requirements.

4.10 Most dosimeters have significant energy dependence at photon and electron energies less than 100 keV, so great care must be exercised when measuring absorbed dose in that energy range.

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

5. Type of facilities and modes of operation used for blood irradiation

5.1 *Self-Contained Blood Irradiators*—Self-contained irradiators may utilize gamma radiation from either ^{137}Cs or ^{60}Co **(4)**, or low energy X-radiation (bremsstrahlung). Units with radionuclides house the radiation source in a protective lead shield (or other appropriate high atomic number material), and usually have a mechanism to move the canister from the load/unload position to the irradiation position. Typically, units with low-energy X-radiation (bremsstrahlung) require less shielding relative to units utilizing gamma radiation. In some cases, irradiator turntables are used.

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 a number of radiation sources in a circular array. The blood product is located at the center of the array where the absorbed-dose distribution is relatively uniform. 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 X-rays (bremsstrahlung) mode) are used primarily for the treatment of tumors. These units may also be used to irradiate blood and blood components. In both types of equipment, the radiation is directed at the blood and blood components using a collimator that creates a well-defined beam of radiation. The blood product is placed in the radiation beam and irradiated statically (that is, neither the source nor the blood product move relative to one another during irradiation).

5.3 *Electron Accelerator (Electron and X-ray (bremsstrahlung) Modes)*—Accelerator-generated radiation is in the form of electrons or X-radiation (bremsstrahlung). Teletherapy accelerators can be used for this purpose. The blood product is placed in the radiation beam and irradiated statically (that is, neither the source nor the blood product move relative to one another during irradiation).

5.3.1 An electron accelerator emits high-energy electrons. 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.

5.3.2 An X-ray (bremsstrahlung) accelerator or generator 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, angular distribution, and dose rates. The physical characteristics of the X-radiation (bremsstrahlung) field depend on the design of the X-rays (bremsstrahlung) converter and the parameters of the electron beam striking the target, that is, the electron energy spectrum, average electron beam current, and beam current distribution on the target.

5.3.3 Spectrum filtration is used to reduce the low energy component of the X-radiation, thus improving the dose uniformity.

6. Radiation source characteristics

6.1 The source of radiation used in a facility considered in this practice consists of sealed ^{60}Co or ^{137}Cs sources that are typically linear rods arranged in one or more planar or cylindrical arrays, X-radiation (bremsstrahlung), 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 **(5)**.

6.3 The half-lives for ^{60}Co and ^{137}Cs are approximately 5.2708 years **(6)** and 30.07 years **(7, 8)**, respectively.

6.4 For gamma sources, the only variation in the source output is the known reduction in the activity caused by radioactive decay. The reduction in the source output and the required increase in the irradiation time to deliver the same dose may be calculated (see 9.3.4) 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-radiation (bremsstrahlung) ranges from approximately 40 keV up to the maximum energy of the electrons incident on the X-ray (bremsstrahlung) 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 for radiation treatment.

7. Dosimetry systems

7.1 *Description of Dosimeter Classes*:

7.1.1 Dosimeters may be divided into four basic classes according to their relative quality and areas of application: primary-standard, reference-standard, transfer-standard, and routine dosimeters. ISO/ASTM Guide 51261 provides information about the selection of dosimetry systems for different applications. All classes of dosimeters, except the primary standards, require calibration before their use.

7.1.1.1 *Primary-Standard Dosimeters*—Primary-standard dosimeters are established and maintained by national standards laboratories for calibration of radiation environments (fields) and other classes of dosimeters. The two most commonly used primary-standard dosimeters are ionization chambers and calorimeters.

7.1.1.2 *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, along with their useful dose ranges, are given in ISO/ASTM Guide 51261 and Table 1.

7.1.1.3 *Transfer-Standard Dosimeters*—Transfer-standard dosimeters are specially selected dosimeters used for transferring absorbed-dose information from an accredited or national

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 1026E 1026
Ionization Chamber	Electrometer	Can be easily applied to the blood-irradiation Dose Range[A]	**(9)**

[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 1026E 1026

TABLE 3 Examples of routine dosimeters

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	**(10, 11)**
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
Optical Waveguide Dosimeters	Photometric means using dual wavelength photometry	1 to 2×10^4	ISO/ASTM 51310
Photo-Fluorescent Dosimeters (for example, LiF)	Fluorimeter	10 to 3×10^5	ASTM E 2304E 2304

standards laboratory to an irradiation facility in order to establish traceability for that facility. These dosimeters should be carefully used under conditions that are specified by the issuing laboratory. Transfer-standard dosimeters may be selected from either reference-standard dosimeters or routine dosimeters taking into consideration the criteria listed in ISO/ASTM Guide 51261 and Table 2.

7.1.1.4 *Routine Dosimeters*—Routine dosimeters may be used for radiation process quality control, dose monitoring and dose mapping. Proper dosimetric techniques, including calibration, shall be employed to ensure that measurements are reliable and accurate. Examples of routine dosimeters, along with their useful dose ranges, are given in ISO/ASTM Guide 51261 and 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 are 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, used to determine the time interval for the irradiation (or the timer setting), is determined using higher-quality reference-standard or transfer-standard dosimeters.

7.2.1 *Timer Setting Calculations*—Reference-standard dosimeter measurements are used to calculate the timer setting required to deliver the specified absorbed dose to the center of the blood and blood component volume, or other reference position.

7.2.1.1 Precise and accurate absorbed-dose measurements are made in simulated product under 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 and blood components.

7.2.2 *Quality Control and Routine Monitoring*—Routine dosimeters may be used for quality control and routine monitoring to help ensure that the product receives the desired dose, and to identify unexpected changes in the process.

7.2.2.1 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, while not exceeding the maximum allowed dose.

7.2.2.2 The absorbed dose may be measured at a reference position (see 10.3.3). Accurate radiation dosimetry at a reference position, which could be the position of the maximum absorbed dose (D_{max}) or minimum absorbed dose (D_{min}) offers a quantitative, independent method to monitor the radiation process.

7.2.2.3 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