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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 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 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 E10, Nuclear Technology and Applications, through Subcommittee E10.01, and by Technical Committee ISO/TC 85, Nuclear energy.

This second edition cancels and replaces the first edition (ISO/ASTM 51939:2002), which has been technically revised.

ISO/ASTM 51939:2005(E)

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-rays (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-rays (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 Guide for Selection and Calibration of 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 60 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

[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] 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.

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 dϵ by dm, where dϵ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm (see ICRU 60).

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

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 60).

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

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-rays (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-rays (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 170. Definitions in ASTM Terminology E 170 are compatible with ICRU 60; 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 rays 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.

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

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.

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

5.1 *Self-Contained Blood Irradiators*—Self-contained irradiators may utilize gamma rays from either ^{137}Cs or ^{60}Co **(4)**, or low energy X-rays (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-rays (bremsstrahlung) require less shielding relative to units utilizing gamma rays. 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-rays (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-rays (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-rays, 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-rays (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-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 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-rays (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.

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]	**(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 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 2304

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 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 measurements made on the product at regular intervals provide the operator and regulatory authorities with an independent quality control record for the process. When D_{min} 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 D_{max} and D_{min} for a given set of operating parameters (for example, 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 with adequate resolution 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 9.3.2 and 10.3.

7.3 *Calibration of Dosimetry Systems*:

7.3.1 Prior to use, the dosimetry system (consisting of a specific batch of dosimeters and specific measurement instruments) shall be calibrated in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. This calibration process shall be repeated at regular intervals to ensure that the accuracy of the absorbed-dose measurement is maintained within required limits. Calibration methods are described in ISO/ASTM Guide 51261.

7.3.2 Irradiation is a critical component of the calibration of the dosimetry system.

7.3.3 *Calibration Irradiation of Reference-Standard or Transfer-Standard Dosimeters*—Calibration irradiations shall be performed at an accredited calibration laboratory, or in-house calibration facility meeting the requirements of ISO/ASTM Practice 51400, that provides an absorbed dose (or absorbed-dose rate) having measurement traceability to nationally or internationally recognized standards.

7.3.4 *Calibration Irradiation of Routine Dosimeters*—Calibration irradiations may be performed per 7.3.3, or at an irradiation facility together with reference- or transfer-standard dosimeters that have measurement traceability to nationally or internationally recognized standards. This clause also applies when reference-standard dosimeters are used as routine dosimeters.

7.3.5 *Measurement Instrument Calibration and Performance Verification*—For the calibration of the instruments, and for the verification of instrument performance between calibrations, see ISO/ASTM Guide 51261, the corresponding ISO/ASTM or ASTM standard for the dosimetry system, and/or instrument-specific operating manuals.

7.4 *Factors That Affect the Response of Dosimeters*:

7.4.1 Factors that affect the response of dosimeters, including environmental conditions and variations of such conditions within the processing facility, shall be known and their effect taken into account (see ISO/ASTM Guide 51261). Examples of routine dosimeters are listed in Table 3, and described in more detail in Annex A1.

7.4.2 The possible energy range for blood irradiation applications is from 40 keV to 5 MeV for photons, and up to 10 MeV for electrons. Care must be taken, therefore, to calibrate the dosimeter using typical energy ranges for routine use.

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 3—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 facility. This documentation shall be retained for the life of the facility. 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.

8.4 For self-contained irradiators, installation qualification may begin prior to the shipment of the irradiator to the customer's site.

9. Operational qualification

9.1 *Objective*—The purpose of operational qualification of an irradiation facility 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 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 distributions in blood-equivalent material and other reference materials, *(3)* characterize absorbed-dose variations when irradiator and processing parameters fluctuate statistically through normal operations, and *(4)* measure the absorbed-dose rate at a reference position within the canister filled with blood or simulated product.

9.1.1 For self-contained irradiators, 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 52116).

9.2 *Dosimetry Systems*—Calibrate the routine dosimetry system to be used at the facility as discussed in 7.3.

9.3 *Irradiator Characterization*—The absorbed dose received by any portion of 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 processing parameters (such as the irradiation time, the product composition and density and the loading configuration).

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 product or simulated product at a reference position (such as the center of the product or simulated product volume) in near worst-case geometry (such as when the product or 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 rate. This measurement of absorbed-dose rate at a reference position may be used when calculating the timer setting necessary to deliver the specified absorbed-dose range.

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 self-contained units, before shipping) the irradiator.

9.3.1.2 Reference- or transfer-standard measurement of absorbed-dose rate at a reference position should be repeated periodically (for example, every two years for a gamma facility) and following any changes to the source, geometry, or other irradiator parameter that could affect absorbed-dose rate.

NOTE 4—To the degree possible, subsequent re-calibrations of dose rate should be performed under similar conditions to allow direct comparison amongst test results. Results obtained when re-calibrating an irradiator should agree with results of previous calibrations, 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.

NOTE 5—When an irradiator's absorbed-dose rate is measured, it is convenient to calibrate the facility's routine dosimetry system concurrently per 7.3. ISO/ASTM Guide 51261 provides guidelines on procedures and numbers of sets of dosimeters needed.

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 samples of blood or simulated product, and identifying the magnitudes and locations D_{max} and D_{min} within the samples. 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.

9.3.2.1 Map the absorbed-dose distribution by placing dosimeters throughout the actual or simulated product. Select placement patterns that can identify the locations of D_{max} and D_{min}.

NOTE 6—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.

9.3.2.2 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 and quantified.

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.

9.3.3.2 Procedures for measuring and correcting for transit dose in terms of transit time are given in ISO/ASTM Guide 51261.

9.3.3.3 In self-contained gamma irradiators, the transit dose should be small relative to the total dose delivered to the blood (for example, less than 1 %) in order to facilitate reproducible absorbed-dose delivery.

9.3.4 *Timer Setting Calculation*—An important calculation in the use of gamma-ray sources is the correction for radioactive decay. For a pure radionuclide source, the reduction in

activity with time is exponential. For an initial activity of A_o (at time = 0), the activity at some later time, t, is given by:

$$A_t = A_o \cdot e^{-\lambda t} \quad (4)$$

where A_t is the source activity at time t. λ, the decay constant for the radionuclide, is defined as:

$$\lambda = \ln(2) / T_{1/2} \quad (5)$$

where $T_{1/2}$ is the half-life for the radionuclide. The half-lives for ^{60}Co and ^{137}Cs are 5.2708 years **(6)** and 30.07 years **(7, 8)**, respectively.

Using 365.2422 days per year **(6)**, the values for λ in Eq 5 for ^{60}Co and ^{137}Cs are:

$$\text{For } ^{60}\text{Co}, \lambda = 3.60054 \times 10^{-4} \text{ day}^{-1} \quad (6)$$

$$\text{For } ^{137}\text{Cs}, \lambda = 6.31119 \times 10^{-5} \text{ day}^{-1} \quad (7)$$

where no round-off has occurred until the final answer.

The decay factor is defined as:

$$\text{Decay Factor} = A_t / A_o = e^{-\lambda t} \quad (8)$$

NOTE 7—Examples for using these equations to obtain decay factors are given as follows: for an elapsed time period of 500 days and using the decay constants calculated in Eq 6 and 7 and substituting into Eq 8, the decay factors for ^{60}Co and ^{137}Cs are 0.835248 and 0.968933, respectively.

Since the absorbed-dose rate due to a radionuclide source also varies exponentially, the dose rate, DR, is given by:

$$DR_t = DR_o \cdot e^{-\lambda t} \quad (9)$$

where DR_t is the dose rate at a time t; DR_o is the dose rate at some earlier time (t = 0) at the same location and under the same irradiation geometry.

The timer setting (TS) necessary to deliver the targeted dose varies inversely with the dose rate and source activity, and is given by:

$$TS_t = TS_o / e^{-\lambda t} \quad (10)$$

where TS_t is the timer setting necessary to deliver the required target dose at a time t; TS_o is the timer setting at some earlier time (t = 0) to deliver the same target dose. Typically for free-standing irradiators with a ^{137}Cs radionuclide source, the timer setting is adjusted (increased) by ~1.1 % every six months. Typically, for free-standing irradiators with a ^{60}Co radionuclide source, the timer setting is adjusted (increased) by ~1.1 % every month.

9.3.4.1 Although the output of gamma-ray sources is expected to be constant (except for radioactive decay), errors may be introduced by the existence of radioactive impurities. For example, ^{134}Cs may be an impurity in ^{137}Cs sources. This could lead to an error in the manufacturer's measurement of source activity. In addition, the dose measurements cannot differentiate the dose contributions from ^{134}Cs and ^{137}Cs. Although the original dosimetry measurements take this into account, ^{134}Cs and ^{137}Cs decay at different rates, which may lead to an error in the timer setting calculations. If the contribution to the central dose rate from the radioimpurity is greater than 1 %, the irradiator manufacturer should provide a timer setting methodology to accurately account for source decay. Periodic remeasurement of the central dose rate using a reference-standard dosimeter may help to minimize the uncertainty introduced by the presence of radioimpurities.

10. Performance qualification

10.1 *Objective*—The purpose of performance qualification is to ensure that the absorbed-dose requirements for a particular product can be satisfied. Typically, the regulatory agency specifies the minimum and maximum absorbed dose for the process. This is accomplished by absorbed-dose mapping (see 10.3) of the specific product (or simulated product) to determine the magnitude and location of D_{max} and D_{min}, and to establish the appropriate values for the timer setting, or other parameter(s) necessary to achieve the absorbed doses within the set requirements.

10.2 *Product Loading Configuration*—A loading configuration for the irradiation should be established for each 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 each type of irradiated 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 each selected product-loading configuration by placing dosimeter sets throughout the product volume or simulated product. Concentrate the dosimeters in regions of D_{max} and D_{min} with fewer dosimeters placed in areas likely to receive intermediate absorbed dose. In many applications, the product is relatively close to the radiation sources, resulting in pronounced absorbed-dose gradients near the periphery of the volume of the sample. It is important, therefore, to choose a dosimeter that is small enough to detect these gradients. Dosimeter film in strips or sheets may be employed to obtain useful information **(12)**.

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

10.3.2 If any changes are made to the irradiator 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 re-verified.

10.3.3 *Reference Position*—Identify a reference position for each loading configuration. This may be, for example, the location of D_{min} or D_{max}, or an alternate location in or on the canister. Dosimeter sets should be placed at the reference position during routine dosimetry, so accessibility should be considered. The absorbed dose at this location shall have a reproducible and documented relationship to the absorbed dose at the locations of D_{min} and D_{max}.

10.4 *Establishing Operating Parameters*—To ensure that the absorbed dose is within specified limits, values of operating parameters should be established for each product, loading configuration, and dose specification. Value(s) of all parameters that affect absorbed dose 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 irradiation facilities, the absorbed dose is controlled by adjusting a single operating parameter such as timer setting. The value that is established for that parameter shall result in an absorbed-dose distribution that is within specified limits throughout the irradiation volume.

11. Routine product processing

11.1 *Operating Parameters and Control*—For product processing, set the operating parameters as established during performance qualification (taking into account source decay, if necessary). All critical process parameters that can affect the absorbed-dose distribution shall be controlled and monitored during routine processing. These parameters include: product loading, timer setting and turntable rotation. 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 minimum dose prescribed for the process. The absorbed dose may be measured at a reference-dose 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 necessary.

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

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 reference-dose position (see 10.3.3 and 11.2). Under predefined conditions of operation, the absorbed dose at the reference-dose position has a quantitative and reproducible relationship with D_{max} and D_{min} (see 10.3.3).

11.2.1.2 *Dosimeter Placement Frequency*—Select a sufficient number of bags 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.

NOTE 8—The absorbed-dose distribution in the simulated product 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.

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.

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

11.2.2.2 *Radiation-sensitive Indicator Placement Frequency*—Select a sufficient number of bags 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, 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. 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 Guides 51261 and 51539, and practices for individual dosimetry systems listed in 2.1 and 2.2).

11.4 *Chilled or Frozen Blood and Blood Components*—Absorbed dose is not a function of the blood or blood product temperature. 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. Determine the temperature of the dosimeter during irradiation of chilled or frozen blood and blood components and apply the appropriate temperature correction. Dosimeters and radiation-sensitive indicators that exhibit a highly temperature-dependent response should not be placed in locations with large temperature gradients. (See ISO/ASTM Guide 51261 and practices for individual dosimetry systems listed in 2.1 and 2.2).

11.5 *Partially Loaded Canisters*—Irradiations may be performed using less product than that used for the initial dose mapping. For partially loaded canisters, the D_{max} received by the product may be greater than the D_{max} measured in the simulated product. Care must be taken, therefore, to ensure that the D_{max} allowed by law (if applicable) is not exceeded during routine use. 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 irradiation volume, and by center-loading the product.

12. Measurement uncertainty

12.1 To be meaningful, a measurement of absorbed dose shall be accompanied by an estimate of uncertainty.

12.2 Components of uncertainty shall be identified as belonging to one of two categories:

12.2.1 *Type A*—Those evaluated by statistical methods, or

12.2.2 *Type B*—Those evaluated by other means.

12.3 Other ways of categorizing uncertainty have been widely used and may be useful for reporting uncertainty. For example, the terms *precision* and *bias* or *random* and *systematic* (non-random) are used to describe different categories of uncertainty.

NOTE 9—The identification of Type A and Type B uncertainties is based on methodology for estimating uncertainties published in 1995 by the

International Organization for Standardization (ISO) in the Guide to the Expression of Uncertainty in Measurement **(13)**. The purpose of using this type of characterization is to promote an understanding of how uncertainty statements are arrived at and to provide a basis for the international comparison of measurement results.

12.4 The accuracy of the absorbed-dose measurement is a function of the dosimetry system used. All dosimeters have environmental dependencies that should be compensated for in the final results (see ISO/ASTM Guide 51261). These corrections introduce uncertainties in the absorbed-dose measurement, and they must be included in the estimate in the evaluation of the dosimetry system's overall uncertainty (see ISO/ASTM Guide 51707).

NOTE 10—ISO/ASTM Guide 51707 defines possible sources of uncertainty in dosimetry performed in radiation processing facilities, and offers procedures for estimating the magnitude of the resulting uncertainties in the measurement of absorbed dose using a dosimetry system. The document defines and discusses basic concepts of measurement, including estimation of the measured value of a quantity, "true" value, error and uncertainty. Components of uncertainty are discussed and methods are provided for estimating their values. Methods are also provided for calculating the combined standard uncertainty and estimating expanded (overall) uncertainty.

12.5 If care is taken in carrying-out this practice and the relevant dosimeter standards, the overall uncertainties in the measurement of absorbed dose (at the 95 % confidence level) should be consistent with the value specified in the relevant dosimeter standard (refer to Tables 1-3).

13. Keywords

13.1 absorbed dose; absorbed-dose mapping; blood and blood products; blood irradiation; dosimeter; dosimetry system; irradiator; ionizing radiation; measurement quality assurance plan; measurement uncertainty; radiation-sensitive indicators; reference-standard dosimeter; routine dosimeter; transfer-standard dosimeter; ICS 17.240

ANNEXES

(informative)

A1. CHARACTERISTICS OF SOME ROUTINE DOSIMETERS

A1.1 Thermoluminescence dosimeter (TLD)

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

Applicable Dose Range: 10^{-4} to 10^{3} Gy

Applicable Dose Rate: 10^{-2} to 10^{10} Gy/s^{-1}

Use: Electron/gamma ray/ X-rays (bremsstrahlung)

Physical Characteristics: After irradiation, 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.

Humidity: Not generally sensitive.

Ambient Light: Not generally sensitive.

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

A1.2 MOSFET dosimeter

Applicable Dose Range: 1 to 200 Gy

Applicable Dose Rate: < 10^{-2} to 10^{8} Gy/s

Use: Electron/Gamma ray/ X-rays (bremsstrahlung)

Physical Characteristics: 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.

For more information see Refs **(10, 11)**.

A1.3 Radiochromic film dosimeter

For more information on this dosimetry system, see ISO/ASTM 51275.

Applicable Dose Range: 1 to 10^{5} Gy

Applicable Dose Rate: < 10^{13} Gy/s^{-1}

Use: Electron/gamma ray/ X-rays (bremsstrahlung)

Physical Characteristics: These dosimeters consist of leuco (colorless) dyes that become intensely colored upon irradiation. Film thicknesses vary from a few micrometers to about 1 mm.

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

Environmental Factors:

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