INTERNATIONAL

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Standard Terminology Relating to Radiation Processing: Dosimetry and Applications[1]

This standard is issued under the fixed designation E3083; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

This terminology covers terms that apply to radiation processing using ionizing radiation. The common radiation fields considered are gamma radiation, X-radiation, and electrons. This treatment is not intended to be exhaustive but reflects special and common terms used in technology and application of interest to Committee E61, specifically, terms included in the E61 set of ISO/ASTM and ASTM standards on radiation processing.

This terminology uses recommended definitions and concepts of quantities, with units, for radiation measurements as contained in the International Commission on Radiation Units and Measurements (ICRU) Report 85a on "Fundamental Quantities and Units for Ionizing Radiation," October 2011.[2] Those terms that are defined essentially according to the terminology of ICRU Report 85a will be followed by ICRU in parentheses. It should be noted that the units for quantities used are the latest adopted according to the International System of Units (SI). This terminology also uses recommended definitions of two JCGM documents, namely "International vocabulary of metrology" (VIM 2012) and "Guide to the expression of uncertainty in measurement" (GUM, 2008).[3] Those terms that are defined essentially according to the terminology of these documents are followed by either VIM or GUM in parentheses. As far as possible, it is also intended to harmonize the definitions with those in Terminology E170, ISO 11139, and ISO 12749-4.

It is recommended that the use of the old units for quantities with special names be avoided; however, if it is deemed necessary to use them for clarity, values of quantities should be expressed first in the new units followed by values in the old units in parentheses. Table X1.1 summarizes the relationship between the old and new units for the quantities of interest.

A term is boldfaced when it is defined in this standard. For some terms, text in italics is used just before the definition to limit its field of application, for example, see **activity**.

1. Scope

1.1 This terminology standard lists terms and definitions related to radiation processing concepts, especially radiation dose measurements. Use of this standard, and the common terminology, will foster clearer communication, and remove ambiguity.

1.2 The use of ionizing radiation for the treatment of commercial products such as the sterilization of medical devices, the reduction of microbial contamination in food or the modification of polymers is referred to as radiation processing. The types of radiation used may be gamma radiation (typically from cobalt-60 sources), X-radiation or accelerated electrons.

1.3 This standard provides terms and definitions for dosimetry for radiation processing concepts dealing with procedures related to operational qualification, performance qualification, and routine processing that may influence absorbed dose in the products, and types of dosimetry systems that may be used during calibration or on a routine basis as part of quality assurance in commercial radiation processing of products.

1.4 When selecting terms and definitions, special care has been taken to include the terms that need to be defined, that is to say, either because the definitions are essential to the correct understanding of the corresponding concepts or because some specific ambiguities need to be addressed.

1.5 The "Discussion" appended to certain definitions offers clarification or examples to facilitate understanding of the

[1] This terminology is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.01 on Dosimetry.

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[2] Available from International Commission on Radiation Units and Measurements (ICRU), 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814.

[3] Document produced by Working Groups of the Joint Committee for Guides in Metrology (JCGM). Available free of charge at BIPM website (http://www.bipm.org).

concepts described. In certain cases, miscellaneous information is also included, for example, the units in which a quantity is normally measured, recommended parameter values, references, etc.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[4]

E170 Terminology Relating to Radiation Measurements and Dosimetry

2.2 *ISO/ASTM Standards:*[4]

ISO/ASTM 51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV

2.3 *Joint Committee for Guides in Metrology (JCGM) Reports:*[3]

JCGM 100:2008, GUM 1995, with minor corrections Evaluation of measurement data – Guide to the expression of uncertainty in measurement

JCGM 200:2012, VIM International vocabulary of metrology – Basic and general concepts and associated terms

2.4 *ICRU and BIPM Documents:*

ICRU 85a Fundamental quantities and units for ionizing radiation[2]

BIPM The International System of Units (SI)[5]

2.5 *ISO Standards:*[6]

12749-4 Nuclear energy, nuclear technologies, and radiological protection – Vocabulary – Part 4: Dosimetry for radiation processing

ISO/TS 11139 Sterilization of health care products – Vocabulary

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

3. Significance and Use

3.1 The purpose of this standard is to facilitate communication and promote common understanding within the professionals in radiation processing research and industry.

3.2 Unambiguous communication of concepts is crucial taking into account the relevant implications that may arise from misunderstandings with regard to equipment and materials involved in the standards dealing with any subject regarding radiation processing activities. Concepts dealing with dosimetry related to radiation processing and procedures for preparation, testing, and using dosimetry systems to determine the absorbed dose are present in all standards developed by E61 and ISO/TC85/WG3 and need to be designated by common terms and described by harmonized definitions in order to avoid misunderstandings.

4. Terminology

4.1 *Terms and Definitions:*

absorbed dose (*D*)**—**quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to matter of mass dm (ICRU), thus

$$D = d\bar{\varepsilon}/dm$$

DISCUSSION—The SI unit of absorbed dose is the gray (Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy=1 J/kg).

absorbed-dose rate ($\dot{D}$)**—**quotient of dD by dt, where dD is the increment of **absorbed dose** in the time interval dt (ICRU), thus

$$\dot{D} = dD/dt$$

DISCUSSION—

(1) The SI unit is $Gy \cdot s^{-1}$. However, the absorbed-dose rate is often specified in terms of its average value over longer time intervals, for example, in units of $Gy \cdot min^{-1}$ or $Gy \cdot h^{-1}$.

(2) In gamma industrial irradiators, dose rate may be significantly different at different locations where product is irradiated.

(3) In electron-beam irradiators with pulsed or scanned beam, there are two types of dose rate: average value over several pulses (scans) and instantaneous value within a pulse (scan). These two values can be significantly different.

absorbed-dose mapping—measurement of **absorbed dose** within an irradiated product to produce a one-, two-, or three-dimensional distribution map of absorbed dose.

DISCUSSION—For a **process load**, such a dose map is obtained using dosimeters placed at specified locations within the process load.

accredited dosimetry calibration laboratory—dosimetry laboratory with formal recognition by an accrediting organization that the dosimetry laboratory is competent to carry out specific activities which lead to **calibration** or calibration verification of **dosimetry system**s in accordance with documented requirements of the accrediting organization.

activity (*A*)**—***of an amount of radionuclide in a particular energy state at a given time*, quotient of $-dN$ by dt, where dN is the mean change in the number of nuclei in that energy state due to spontaneous nuclear transitions in the time interval dt (ICRU), thus

$$A = -dN/dt$$

Unit: s^{-1}

The special name for the unit of activity is becquerel (Bq), thus $1\ Bq = 1\ s^{-1}$.

DISCUSSION—

(1) The former special unit of activity was the curie (Ci).

$1\ Ci = 3.7 \times 10^{10} s^{-1}$.

[4] 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.

[5] Available in electronic form at www.bipm.org/en/si/si_brochure/

[6] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

(2) The 'particular energy state' is the ground state of the nuclide unless otherwise specified.
(3) The activity of an amount of radionuclide in a particular energy state is equal to the product of the **decay constant**, λ, for that state and the number of nuclei in that state (that is $A=N\lambda$).

alanine dosimeter—specified quantity and physical form of the radiation-sensitive material alanine and any added inert substance such as a binder.

analysis wavelength—wavelength used in a spectrophotometric instrument for the measurement of optical absorbance or reflectance.

approved laboratory—laboratory that is a recognized national metrology institute, or has been formally accredited to ISO/IEC 17025, or has a **quality system** consistent with the requirements of ISO/IEC 17025.

Discussion—
(1) A recognized national metrology institute or other calibration laboratory accredited to ISO/IEC 17025 should be used in order to ensure **traceability** to a national or international standard.
(2) A calibration certificate provided by a laboratory not having formal recognition or accreditation will not necessarily be proof of traceability to a national or international standard.

beam length—dimension of the irradiation zone along the direction of product movement, at a specified distance from the accelerator window.

Discussion—
(1) For graphic illustration, see ISO/ASTM 51649.
(2) This term usually applies to electron irradiation.
(3) Beam length is therefore perpendicular to beam width and to the electron beam axis.
(4) In case of product that is stationary during irradiation, 'beam length' and 'beam width' may be interchangeable.

beam width—dimension of the irradiation zone perpendicular to the direction of product movement, at a specified distance from the accelerator window.

Discussion—
(1) For graphic illustration, see ISO/ASTM 51649.
(2) This term usually applies to electron irradiation.
(3) Beam width is therefore perpendicular to beam length and to the electron beam axis.
(4) In the case of product that is stationary during irradiation, 'beam width' and 'beam length' may be interchangeable.
(5) Beam width may be quantified as the distance between two points along the dose profile, which are at a defined fraction of the maximum dose value in the profile.
(6) Various techniques may be employed to produce an electron beam width adequate to cover the processing zone; for example, use of electromagnetic scanning of a pencil beam (in which case beam width is also referred to as scan width), defocusing elements, and scattering foils.

bremsstrahlung—broad-spectrum electromagnetic radiation emitted when an energetic charged particle is influenced by a strong electric or magnetic field, such as that in the vicinity of an atomic nucleus.

Discussion—
(1) In radiation processing, bremmstrahlung photons with sufficient energy to cause ionization are generated by the deceleration or deflection of energetic electrons in a target material. When an electron passes close to an atomic nucleus, the strong coulomb filed causes the electron to deviate from its original motion. This interaction results in a loss of kinetic energy by the emission of electromagnetic radiation. Since such encounters are uncontrolled, they produce a continuous photon energy distribution that extends up to the maximum kinetic energy of the incident electron.
(2) The bremsstrahlung spectrum depends on the electron energy, the composition and thickness of the target, and the angle of emission with respect to the incident electron.

calibration—set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

Discussion—Calibration conditions include environmental and irradiation conditions present during irradiation, storage and measurement of the dosimeters that are used for the generation of a **calibration curve**.

calibration curve—expression of the relation between indication and corresponding measured **quantity value** (VIM).

Discussion—In radiation processing standards, the term '**dosimeter response**' is generally used for 'indication'.

calorimeter—assembly consisting of calorimetric body (absorber), thermal insulation, and temperature sensor with wiring.

cellulose triacetate dosimeter——piece of CTA film that, during exposure to ionizing radiation, exhibits a quantifiable change in **specific net absorbance** as a function of **absorbed dose**.

ceric-cerous dosimeter—specially prepared solution of ceric sulfate and cerous sulfate in sulfuric acid, individually sealed in an appropriate container such as a glass ampoule, where the radiation-induced changes in electropotential or optical absorbance of the solution is related to **absorbed dose** to water.

charged-particle equilibrium (referred to as *electron equilibrium* in the case of electrons set in motion by photon irradiation of a material)——condition in which the kinetic energy of charged particles (or electrons), excluding rest mass, entering an infinitesimal volume of the irradiated material equals the kinetic energy of charged particles (or electrons) emerging from it.

combined standard measurement uncertainty——standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model (VIM).

Discussion—
(1) It is also referred to as 'combined standard uncertainty.'
(2) In case of correlations of input quantities in a measurement model, covariances must also be taken into account when calculating the combined standard measurement uncertainty.

compensating dummy—see **simulated product**.

coverage factor *(k)***—**number larger than one by which a **combined standard measurement uncertainty** is multiplied to obtain an **expanded measurement uncertainty-** (VIM).

Discussion—A coverage factor, *k*, is typically in the range of 2 to 3.

decay constant (λ)—*of a radionuclide in a particular energy state*, quotient of –d*N/N* by d*t*, where d*N/N* is the mean fractional change in the number of nuclei in that energy state due to spontaneous nuclear transformations in the time interval d*t* (ICRU), thus

$$\lambda = \frac{-\mathrm{d}N/N}{\mathrm{d}t}$$

Unit: s^{-1}

DISCUSSION—The quantity (ln 2)/λ is commonly called the half-life, $T_{½}$, of the radionuclide; that is, the time taken for the **activity** of an amount of radionuclide to become half its initial value.

depth-dose distribution—variation of **absorbed dose** with depth from the incident surface of a material exposed to a given radiation.

dichromate dosimeter—solution containing silver and dichromate ions in perchloric acid in an appropriate container such as a sealed glass ampoule that indicates **absorbed dose** by change (decrease) in absorbance at a specified wavelength.

dose uniformity ratio—ratio of the maximum to the minimum **absorbed dose** within the irradiated product.

DISCUSSION—The concept is also referred to as the max/min dose ratio.

dosimeter—device that, when irradiated, exhibits a quantifiable change that can be related to **absorbed dose** in a given material using appropriate measurement instruments and procedures.

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.

dosimeter response—reproducible, quantifiable change produced in the **dosimeter** by ionizing radiation.

DISCUSSION—

(1) The dosimeter response value, obtained from one or more measurements, is used in the estimation of the **absorbed dose**.

(2) The response value may be obtained from such measurements as optical absorbance, peak-to-peak distance in EPR spectra, or electropotential between solutions.

dosimeter/dosimetry system characterization—determination of performance characteristics, such as useful dose range, reproducibility, and the effects of influence quantities, for a **dosimeter/dosimetry system** under defined test conditions.

dosimeter set—one or more **dosimeters** used to measure **absorbed dose** at a location and whose average response is used to determine absorbed dose at that location.

dosimetry—measurement of **absorbed dose** by the use of a **dosimetry system**.

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

electron beam energy—kinetic energy of the accelerated electrons in the beam, Unit: J.

DISCUSSION—

(1) Electron volt (eV) is often used as the unit for electron beam energy where 1 eV = $1.602 \cdot 10^{-19}$J.

(2) In radiation processing, where beams with a broad electron energy spectrum are frequently used, the terms most probable energy (E_p) and average energy (E_a) are common. They are linked to the practical electron beam range (R_p) and half-value depth (R_{50}) by empirical equations.

electron energy spectrum—particle fluence distribution of electrons as a function of energy.

electron equilibrium—charged-particle equilibrium for electrons.

ethanol-chlorobenzene dosimeter—partly deoxygenated solution of chlorobenzene (CB) in 96 volume % ethanol in an appropriate container, such as a flame-sealed glass ampoule, used to indicate **absorbed dose** by measurement of the amount of HC1 formed under radiation.

expanded uncertainty—quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the **measurand** (GUM).

DISCUSSION—

(1) Expanded uncertainty is obtained by multiplying the **combined standard measurement uncertainty** by a **coverage factor**, the value of which determines the magnitude of the 'fraction'.

(2) Expanded uncertainty is also referred to as 'overall uncertainty'.

Fricke dosimeter—air-saturated solution of ferrous sulfate or ferrous ammonium sulfate that indicates **absorbed dose** by an increase in optical absorbance at a specified wavelength.

good manufacturing practice (GMP)—procedures established and exercised throughout the production, manufacturing, processing, packing, and distribution of foods, encompassing maintenance of sanitation systems, quality control and **quality assurance**, qualification of personnel and other relevant activities, to ensure the delivery of a commercially acceptable and safe product.

influence quantity—quantity that, in a direct measurement, does not affect the quantity that is actually measured, but affects the relation between the indication and the measurement result (VIM).

DISCUSSION—In radiation processing dosimetry, this term includes temperature, relative humidity, time intervals, light, radiation energy, absorbed-dose rate, and other factors that might affect dosimeter response, as well as quantities associated with the measurement instrument.

in-situ/in-plant calibration—calibration where the dosimeter irradiation is performed in the place of use of the routine dosimeters.

DISCUSSION—In-situ/in-plant calibration of **dosimetry systems** refers to irradiation of dosimeters along with reference or transfer standard dosimeters, under operating conditions that are representative of the routine processing environment, for the purpose of developing a **calibration curve** for the **routine dosimetry systems**.

installation qualification (IQ)—process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.