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Standard Guide for Operational Qualification of Gamma Irradiators¹

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1. Scope

1.1 This document provides guidance on operational qualification (OQ) tests to meet the OQ requirements defined in ISO 11137-1, ISO 14470, ISO/ASTM 51702, and ISO/ASTM 52303 for gamma irradiators.

1.1.1 The types of OQ tests are discussed to help the user gain an increased understanding of operational aspects of their irradiator and determine which OQ tests are appropriate for the assessment of irradiator change.

1.1.2 The facility should assess the rationale for the OQ tests chosen and for the ones that have been deemed to be unnecessary.

1.2 Specific requirements for OQ are dependent on the application of the irradiation process and are not within the scope of this guide. For example, requirements for OQ when sterilizing healthcare products can be found in ISO 11137-1.

1.3 A change to the irradiator is a component of the change control process. The OQ testing following the irradiator change is determined as part of the change control documentation and should include rationale to support decision(s) on which tests are required to be completed.

1.4 For an OQ study following an irradiator change, the required OQ tests are defined procedurally with established acceptance criteria. (The OQ tests in the appendixes have examples of defined acceptance criteria with a rationale for the acceptance.) When multiple tests are used in the assessment of change, no individual OQ test should be solely relied upon; rather, the composite of OQ test results should be used to help provide a clear justification for the conclusion regarding irradiator change.

1.5 Many calculations in this guide were completed using Microsoft Excel (for example, ANOVA, t -test, p -value), but numerous other software tools are commercially available.

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 appro-*

priate 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:²

E2232 Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications

E3083 Terminology Relating to Radiation Processing: Dosimetry and Applications

2.2 ISO/ASTM Standards:²

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing

52303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

52628 Practice for Dosimetry in Radiation Processing

52701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

2.3 ISO Standards:³

ISO 11137-1:2006 Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 11137-3:2017 Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control

ISO/TS 11137-4:2020 Sterilization of health care products — Radiation — Part 4: Guidance on process control

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² For referenced 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 American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

ISO 14470:2011 Food irradiation — Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food

ISO/IEC 17043:2010 Conformity assessment — General requirements for proficiency testing

3. Terminology

3.1 Definitions:

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

3.1.1.1 *Discussion*—Absorbed-dose mapping is often referred to as dose mapping (DM). Dose mapping is the measurement of dose distribution and variability in material irradiated under defined conditions (ISO 11137 Part 1).

3.1.2 *critical path (of an irradiator), n*—positions within an irradiator that significantly contribute to the total absorbed dose.

3.1.3 *dose uniformity ratio (DUR), n*—ratio of the maximum to the minimum absorbed dose within the irradiated product.

3.1.4 *dose zone, n*—a volume of discrete point(s) within a process load that receives doses that are defined as equivalent.

3.1.4.1 *Discussion*—(1) The dose zone is also referred to as a dose position. (2) Equivalency is generally determined based on a standard error about a mean and is often defined as a level of significance (that is, 0.05 alpha for a sampling distribution of the mean (*t*-distribution)). See ISO/ASTM 52303 for a discussion of Minimum Detectable Difference using the *t*-distribution.

3.1.5 *effective density, n*—bulk density multiplied by the ratio of product width to the designed maximum width where width dimension is the dimension perpendicular to the source of radiation.

3.1.5.1 *Discussion*—The effective density helps to correlate the minimum dose rate for the bulk density (that is, fully loaded irradiation container) to the minimum dose rate for the effective density (that is, center-loaded product).

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

3.1.7 *irradiation container, n*—holder in which process load is transported through the irradiator.

3.1.8 *full OQ, n*—a process to establish the irradiator performance baseline for a new irradiator or an existing irradiator following a major irradiator change.

3.1.8.1 *Discussion*—The dose mapping experiments performed directly after a major change activity to determine the effects of the change(s) on the magnitude of dose, dose distribution and variability of dose is often called an irradiator requalification. The full OQ process is used to initially establish or to re-establish the irradiator baseline.

3.1.9 *irradiator pathway, n*—unique product path through the irradiator.

3.1.9.1 *Discussion*—An irradiator may have more than one pathway; each pathway requires OQ dosimetry. An irradiator may have multiple source rack configurations; each source rack configuration is considered a separate pathway, and requires OQ dosimetry. Off-carrier and research loop irradiations are considered separate pathways.

3.1.10 *maximum product stack dimensions, n*—the maximum width, length and height of the process load.

3.1.10.1 *Discussion*—The process load volume is less than the available irradiation container volume to allow the designed airgap between the process load and the irradiation container wall.

3.1.11 *mini-grid, n*—an OQ grid with a reduced set of dosimeter placements developed from the results of quiet system studies as part of a full OQ.

3.1.11.1 *Discussion*—The mini-grid typically includes the absolute and equivalent $D_{\max}$ and $D_{\min}$ positions that are within the minimum detectable difference. As a guideline, a mini-grid could be used where the variable under study is a dose distribution characteristic. A mini-grid is not used when the variable under study is exclusively dose magnitude.

3.1.12 *mini-map, n*—an OQ study using a mini-grid.

3.1.12.1 *Discussion*—When a mini-map is used, dosimeters are placed in expected $D_{\min}$ and $D_{\max}$ zones.

3.1.13 *operational qualification (OQ), n*—process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

3.1.14 *OQ grid, n*—facility-defined dosimeter positions utilized during the OQ quiet system studies that contain adequate positions to measure the absolute and equivalent $D_{\max}$ and $D_{\min}$ positions for a defined density range.

3.1.14.1 *Discussion*—The OQ grid contains intermediate-dose positions that are not equivalent $D_{\min}$ or $D_{\max}$ zones. The OQ grid is also referred to as the Irradiator Qualification Grid, or facility-defined baseline grid. The OQ grid is irradiator specific. A validated mathematical method may be used to establish or verify the OQ grid.

3.1.15 *performance qualification (PQ), n*—process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting specification.

3.1.16 *process load, n*—a volume of material with a specified product loading configuration irradiated as a single entity.

3.1.17 *quiet system, n*—a processing condition in the irradiator whereby only fully-loaded irradiation containers of product or simulated product are present in the irradiator with a defined variation in density.

3.1.17.1 *Discussion*—During the quiet system study, there are no changes in process load dimensions, cycle time or product density. The fully loaded irradiation containers may occupy the entire irradiator, or for an irradiator with two or more parallel source racks, the critical path of the irradiator. (Refer to 3.1.2.) Fully-loaded irradiation containers occupy the