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Standard Guide for Operational Qualification of Gamma Irradiators[1]

This standard is issued under the fixed designation E3270; 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.

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 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:*[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

[1] This guide is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.03 on Dosimetry Application.

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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.

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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

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entire irradiator, or as a minimum, any irradiation container adjacent to or between the source and a container being mapped should contain material of the same density. See the definition of *critical path* for further detail.

3.1.18 *reduced height OQ, n*—an OQ study utilizing a phantom material height that is less than the height available within the irradiation container.

3.1.18.1 *Discussion*—The reduced height OQ dose mapping may be performed to determine the effects of the change(s) on the magnitude of dose, dose distribution and variability of dose. The reduced height OQ process is used to confirm that there has been no significant change in the dose distribution. The reduced height OQ is sometimes referred to as a reduced OQ (that is. a subset of full OQ tests).

3.1.19 *reduced length OQ, n*—an OQ study utilizing a phantom material height that is less than the length available within the irradiation container.

3.1.19.1 *Discussion*—The reduced length OQ dose mapping may be performed to determine the effects of the change(s) on the magnitude of dose, dose distribution and variability of dose.

3.1.20 *reference material, n*—homogenous material of known radiation absorption and scattering properties used to establish characteristics of the irradiation process, such as dose distribution and reproducibility of dose delivery.

3.1.20.1 *Discussion*—Reference material is sometimes referred to as phantom material. Refer to Appendix X2 for a list of reference materials.

3.1.21 *spatial resolution, n*—the physical space a dosimeter occupies and the subsequent dose gradient the dosimeter is understood to represent.

3.1.22 *timer setting, n*—defined time interval during which product is exposed to radiation at an individual irradiation position.

3.1.22.1 *Discussion*—For a shuffle-dwell irradiator the timer setting is the time interval from the start of one shuffle-dwell cycle to the start of the next shuffle-dwell cycle. For a stationary irradiator, the timer setting is the total irradiation time. The timer setting is also referred to as 'Cycle Time' (CT).

4. Significance and Use

4.1 Operational qualification (OQ) will be used to demonstrate that the irradiator, as installed, is capable of operating and delivering dose to product being irradiated with defined acceptance criteria by determining dose distribution and magnitude through dose mapping exercises and relating these distributions to process parameters.

4.2 The principle objectives of OQ are to:

4.2.1 Establish the dose distribution and create a baseline PQ grid for mapping actual product,

4.2.2 Establish the relationship for dose uniformity ratio (DUR) as a function of density,

4.2.3 Establish the relationship for cycle time (CT) as a function of density and source activity, and

4.2.4 Establish the relationship for minimum dose (kGy) as a function of density, cycle time and source activity.

4.3 OQ exercises could augment or replace PQ exercises. It is the facility's responsibility to document the rationale when using OQ data for PQ purposes.

4.4 A design of experiments approach may help rationalize the types of OQ tests needed. For some irradiator changes, the minimum number of densities may be different depending on the degree of anticipated change in dose distribution. These decisions should be covered through a documented change control process. See ISO/ASTM 52701.

4.5 This guide is not intended to address OQ requirements in research or experimental irradiators.

4.6 An irradiation facility is able to process different process load configurations. For example, an irradiation container may be designed to accommodate boxes, sacks and drums. It is important to consider OQ studies that characterize the irradiator for different irradiation geometries.

4.7 The bulk density, dimensions and atomic composition are important properties in dose mapping. See Appendix X2 for examples of materials for potential use in OQ studies.

5. OQ Validation Activities

5.1 OQ tests for assessment of irradiator changes are described in Table 1. Also refer to ISO 11137-1:2006, Table A.11, Table A.1 (for healthcare products), and ISO 14470 (for food products).

5.2 When OQ dosimetry is completed following an irradiator change, the irradiator is assessed for change relative to the baseline irradiator qualification, and possibly relative to the irradiator commissioning. This allows the detection of change in dose magnitude and dose distribution. Even though great care is taken to minimize change following irradiator loadings, change in the dose distribution may still occur over time.

5.3 A repeat of the full OQ or a portion thereof (at a frequency defined by the facility) will help to determine the degree of change, redefine the irradiator characteristics and help to demonstrate the continued effectiveness of the radiation process.

5.4 Table 2 describes potential types of OQ dose mapping associated with full OQ activities.

5.5 Tables 1 and 2 refer to facility-defined OQ grid or a mini-OQ grid. It may be necessary to demonstrate the mini-OQ grid will include the D_{min} and D_{max} zones before it is utilized. For example, it may be necessary to utilize the facility-defined OQ grid until it has been demonstrated that the mini-OQ grid is accurate for all tests to demonstrate the mini-OQ grid is adequate.

6. OQ Acceptance Criteria

6.1 For an OQ study following an irradiator change, the set of OQ tests is defined procedurally with established acceptance criteria. (The OQ tests in the appendixes have examples of defined acceptance criteria with a rationale behind the acceptance.) It is important to state that when multiple tests are used in the determination of change, that no single test is solely

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TABLE 1 OQ Tests for Assessment of Irradiator Change

Irradiator Change	Type of OQ Dose Mapping	Minimum Number of Densities	Minimum Number of Irradiation Containers Mapped per Density	Type of OQ Grid
Addition, Removal or Reconfiguration of Radionuclide (without expected change in the dose distribution)	OQ Dose Mapping for one irradiator path.	Two[A]	Three	Facility-defined OQ Grid
Addition, Removal or Reconfiguration of Radionuclide (with expected change in the dose distribution)	OQ Dose Mapping for each irradiator path. Note: Other studies defined in 'New Irradiator' may not have to be done since the fundamental irradiator characteristics may not have changed, but each test under 'new irradiator' has to be evaluated.	Three	Three	Facility-defined OQ Grid
New Irradiation Containers	OQ Dose Mapping for each irradiator path.	Three	Three	Mini-OQ grid
Replacement of Irradiation Containers (no change in design)	OQ Dose Mapping for one irradiator path.	One	Three	Facility-defined OQ Grid
Changes in Irradiation Pathway (that is, redesign or relocation of product path)	OQ Dose Mapping for each irradiator path. Note: Other studies defined in 'New Irradiator' should be evaluated. Off-carrier and static position OQ (as per above)	Three	Three	Facility-defined OQ Grid
Changes in Source Rack Configuration (that is, new rack or change in source-to-product distance	OQ Dose Mapping for each irradiator path. Note: Other studies defined in 'New Irradiator' should be evaluated.	Three	Three	Facility-defined OQ Grid
Redesign of the Source Rack (with change in dose distribution)	OQ Dose Mapping for each irradiator path. Note: Other studies defined in 'New Irradiator' should evaluated.	Three	Three	Facility-defined OQ Grid
Redesign of the Source Rack (with no change in dose distribution)	OQ Dose Mapping for each irradiator path. Note: Other studies defined in 'New Irradiator' should be evaluated.	One	Three	Facility-defined OQ Grid
Replacement of Source or Guide Cables, or both	IQ is needed. OQ required but limited to equipment testing.	None	None	None
Redesign or Replacement of the Source Drive System	OQ Dose Mapping to remeasure Process Interruption.	One	One (Refer to Table 2)	Facility-defined OQ Grid
Changes in Type of Cycle Timer	IQ is needed. OQ required but limited to equipment testing and calibration.	None	None	None
Changes to Type of Irradiator Radiation Safety Monitoring Devices	IQ is needed. OQ required but limited to equipment testing and calibration.	None	None	None

[A] In the case where the facility processes a very limited product density range, it is possible to complete the OQ using one reference material density.

relied upon; rather, the composite of OQ tests are used with a clear justification behind the conclusion regarding irradiator change.

6.2 The OQ tests given in Tables 1 and 2 should have documented acceptance criteria, or a rationale as to why one is not required.

6.2.1 Dose mapping following the addition, removal or reconfiguration of radionuclide is an example of an OQ test that requires documented acceptance criteria.

6.2.2 Source interrupt studies are an example of an OQ test that may not require acceptance criteria since the test is conducted to determine the impact of source interrupt on D_{min}

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TABLE 2 Types of OQ Dose Mapping

Type of OQ Dose Mapping	Minimum Number of Densities	Minimum Number of Irradiation Containers Mapped per Density	OQ Dose Mapping Grid
OQ Dose Mapping for each irradiator path. See 9.1, 9.2	Three[A]	Three	Facility-defined OQ Grid
Off-carrier OQ for each location. See 9.3	One (represents routine processing density). It may be acceptable for a mini-map to replace OQ.	Three	Facility-defined OQ Grid
Static irradiation. See 9.4	One (represents routine processing density) depending on the required processing range. Mini-map may suffice if completed routinely.	One	Facility-defined OQ Grid
Cycle time change. See 9.5	One	One at the beginning or end of each product row	Mini-OQ grid
Process Interruption. See 9.6	One[B]	One located where maximum process interrupt dose contribution is most significant. Additional containers may be used to ensure maximum dose is captured.	Facility-defined grid for characterization of process interruption
Center Loading. See 9.7	One	One center loaded container, and one adjacent full container.	Mini-OQ grid
Reduced length irradiation container. See 9.8	One	One reduced length irradiation container, and one adjacent full container.	Mini-OQ grid
Repeatability of dwell through the irradiator. See 9.9	One	Facility specific (that is, every irradiation container, or with a defined number of irradiation containers depending on size of source pass).	One dosimeter near D_{min} location. One dosimeter near D_{max} location
Density Variation within irradiator. See 9.10	Two or Three	One at the beginning, one near the middle and one at the end of each density.	Mini-OQ grid
Reduced height irradiation container. See 9.11	One	One reduced height irradiation container, and one adjacent full container.	Mini-OQ grid
Mixed density within irradiation container. See 9.12	Multiple densities within one irradiation container[C]	One, Two or Three	Facility-defined OQ Grid

[A] In the case where the facility processes a very limited product density range, it is possible to complete the full OQ using one reference material density.
[B] The impact of process interruption will likely be dependent on the bulk density. The quantification of impact from a single density may not fully assess the impact over a range of densities.
[C] Depending on what is representative of actual processing conditions.

and D_{max} (that is, Gy/transit/MCi). Those values can be used to establish facility rules for source interrupts.

6.3 Different tools may be used to remove potential subjectivity from the analysis since the results often provide unambiguous information regarding change in the DUR or throughput.

6.3.1 The ANOVA is a test of equivalency of multiple means by comparison of 'between' and 'within' treatment means by an *F*-test.

6.3.1.1 The ANOVA test indicates, at a chosen level of confidence, where a statistically significant difference exists in the DUR mean or throughput mean between the current study and the defined baseline OQ study. See Appendix X14.

6.3.2 The *T*-test (Paired Two Sample for Means Analysis) is a pair-wise comparison of two samples where data points in each sample are concurrently generated.

6.3.2.1 The *T*-test (Paired Two Sample for Means Analysis) can be used to determine whether measurements following an

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irradiator change are likely to have come from distributions with equal population means (assuming that the variances of both populations are not equal). See Appendix X15.

6.3.3 The ANOVA test for curve coefficients (p-value) can be used to compare DUR and throughput following an irradiator change and can be performed at one or more reference material densities. See Appendix X16.

6.3.3.1 This test is a comparison of two samples where elements of each population are paired by category using an F-test and resulting p-value.

6.3.4 The chi-square ($\chi 2$) goodness of fit test is a test of fit of a distribution estimate from a sample equivalent to a specified distribution where elements are categorically partitioned.

6.3.4.1 The chi-square ($\chi 2$) goodness of fit test can used to compare the observed sample distribution with the expected probability distribution. Chi-Square goodness of fit test determines how well theoretical distribution (for example, normal distribution) fits the empirical distribution. See Appendix X17.

6.3.5 Normalized error (E_n) test is a version of a two-sample t-test to determine if two independent samples are drawn from the same population.

6.3.5.1 Normalized error (E_n) is a statistical evaluation that can be used to compare absorbed-dose distributions before and after the irradiator change. In this evaluation, the uncertainty in the measurement result is taken into account. See Appendix X18.

6.4 For a new irradiator, the OQ studies are used to establish the fundamental irradiator relationships such as CT as a function of density, and DUR as a function of density. The acceptance criteria may be based on the irradiator manufacturer's performance estimate, or on the measured performance from similar irradiator designs.

6.5 For an irradiator change that is not expected to lead to a significant change in the dose distribution (for example, source loading), the OQ studies are used to confirm that there has not been a significant change in the dose distribution. The acceptance criteria may be based on the OQ studies that were used to establish the original baseline performance.

6.6 For an irradiator change that has led to a significant change in the dose distribution (for example, adding structural material to the irradiation container), the OQ studies are used to re-establish the fundamental irradiator relationships such as CT and DUR as a function of density. The acceptance criteria may be based on the originally measured irradiator performance.

6.7 In a typical shuffle-and-dwell irradiator, the actual cycle time consists of time when the irradiation container dwells statically and the time for the irradiation container to move to the next dwell position (or from the last dwell position). For many irradiator designs, the proportion of static dwell time and movement time may vary through the irradiator. The potential impact is considered during OQ dosimetry, and scalability of dose exists over a large dose range. Care should be taken when applying the OQ performed at high-dose levels (that is, sterilization doses) to low-dose levels (that is, phytosanitary doses) where the actual time to shuffle the irradiation container becomes more significant relative to the cycle time.

6.8 The facility is responsible for selecting a confidence level as part of establishing acceptance criteria.

7. Mathematical Methods

7.1 Mathematical methods can simulate the transport of photons and electrons through the irradiator and product, taking into account the absorption and scattering by materials. The application requires an accurate knowledge of the sources, their activity distribution and their composition and position within the source rack, as well as the irradiation containers, the irradiator support structures and the actual product or simulated material.

7.2 Mathematical methods can be used in the estimation of absorbed dose in radiation-processing applications.

7.3 Mathematical methods should first be validated through comparison with reliable and traceable dosimetric measurements. This process is known as benchmarking and provides confidence that the mathematical methods may be used to complement or replace some OQ dosimetry exercises. Refer to Guide E2232.

7.4 Mathematical methods that have been validated can be used to:

7.4.1 Assist in establishing and optimizing OQ grids and in the application of dose measurements or of the analysis thereof,

7.4.2 Design irradiators, and optimize a subsequent change in the irradiator,

7.4.3 Optimize the source loading in a gamma irradiator,

7.4.4 Identify the positions of dosimeters used in an OQ coordinate system,

7.4.5 Estimate the effect of source transits in gamma applications,

7.4.6 Estimate the impact of reduced height irradiation container(s), including the adjacent full irradiation container,

7.4.7 Estimate the effect of CT changes within the irradiator,

7.4.8 Estimate the effect of density variations within an irradiation container and within the irradiator,

7.4.9 Estimate the dose distribution within a complex medical device, and assist in the validation of a process before PQ dose mapping, and

7.4.10 Estimate the impact of changes in product composition, or configuration.

7.5 For more information on the use of mathematical modelling as a compliment to dose mapping, refer to Guide E2232.

8. Prerequisites for the Completion of OQ

8.1 Facility IQ to be completed:

8.1.1 Dosimetry system calibration (with a defined uncertainty) traceable to a national or international standard,

8.1.2 Operating procedures for the irradiator and associated conveyance system(s),

8.1.3 Process and ancillary equipment, including associated software, tested to verify operation to design specifications

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8.1.4 Verification that irradiation containers are built to specification within manufacturer's tolerance,

8.1.4.1 Examples of irradiation container checks are total weight, thickness of key structural materials and overall length, width of the internal and external dimensions,

8.1.5 Any modifications made to the irradiator during installation documented, and

8.1.6 The total activity of the radiation sources and a record of the location of each radiation source recorded.

8.1.6.1 Performing an independent radiation source audit during installation and confirmation that the modules have been removed and installed correctly will help to ensure the source loading is executed as planned.

9. OQ Dose Mapping Study Procedures

9.1 *Dosimeter Selection and Placement Strategy:*

9.1.1 Information from previous irradiator studies, mainly OQ studies at similar densities, may be used to concentrate dosimeter placement in order to capture minimum and maximum dose zones.

9.1.2 Selection of dosimeter positions for dose mapping should include areas of suspected high dose gradients based on a physical assessment of the materials and their composition.

9.1.3 Gamma OQ generally utilizes homogeneous reference materials, although materials that simulate actual product can be used. As such, there may be dose gradients within the material that can be measured by the strategic placement of dosimeters.

9.1.3.1 Dose gradients within process loads are typically measured over distances on the order of centimeters (for higher-density materials) to tens of centimeters (for lower-density materials). The source-product geometry and irradiator design will also be a factor in the dose gradients within the process load.

9.1.4 When placing dosimeters for OQ dose mapping, it may be necessary to use a different dosimeter type than used in routine processing, or for other locations during the dose map (for example, radiochromic films with alanine pellets). If multiple dosimeter types are employed, there should be some locations chosen where both types can be co-located in order to confirm if a bias in dose exists. It may necessary to correct any bias.

9.1.5 It is possible to utilize a dosimetry system for OQ dose mapping at an operating range that is different than the range used for routine processing. In order for this method to be valid, it is important to demonstrate the proportionality between key irradiator parameters of the facility and dose to product.

9.1.6 The use of mathematical methods to identify appropriate dosimeter locations for OQ dose mapping, or to predict dose map results may be valuable. Refer to Guide E2232 for guidance.

9.2 *OQ Dose Mapping Study Execution:*

9.2.1 In ISO/ASTM Practice 51702, ISO 11137-1 (healthcare products) and ISO 14470 (food products), OQ dose mapping is performed to characterize the irradiator with respect to the dose distribution and reproducibility of absorbed dose delivery. This should be performed in accordance with a formal validation program and cover the density range that will be used in actual processing.

9.2.2 OQ dose mapping studies require an established OQ grid. The OQ grid defines all facility-defined dosimeter positions used for dose mapping homogeneous reference material. The reference material may occupy the maximum product stack dimensions, or use a reduced-length, reduced-width or reduced-height stack, depending on the type of OQ study.

9.2.3 Statistical analyses of the results can be applied to establish the values of minimum and maximum doses, zones of equivalent extrema doses, and, if necessary, identification of dose zones that are not likely to be either D_{max} or D_{min} zones.

9.2.4 Material densities should be within the density range for which the irradiator is used, and this range may be less than the facility's design range. Refer to Table 2 for details associated with the type of OQ grid to be used, and the minimum number of irradiation containers and the minimum number of densities for each OQ study.

NOTE 1—The facility may consider dose mapping additional densities in order to gain additional performance information.

9.2.5 Determine the absorbed-dose distribution for all irradiator pathways using the defined dosimeter grid in Table 2.

9.2.6 For a given OQ test, select a sufficient number of routine dosimeters for dose mapping the irradiation containers defined in Table 2 with the applicable dosimeter grid. Refer to Fig. 2 for an example of a dosimeter grid. All dosimeters used for a set of OQ studies should come from the same dosimeter stock, if possible.

9.2.7 Perform OQ dose mapping by placing dosimeters in a number of process loads of reference material that fills the container to its design volume limits. The number of process

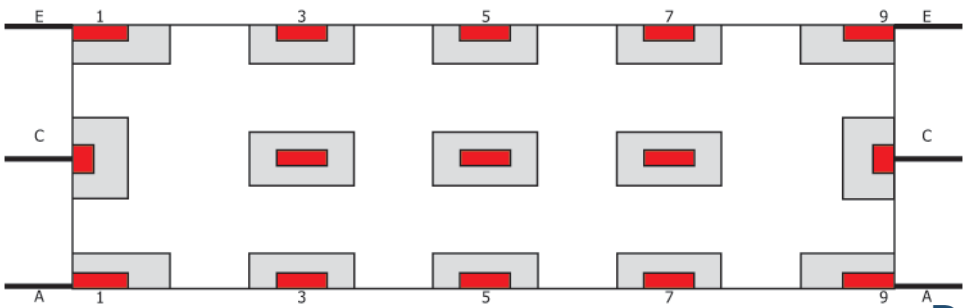

FIG. 1 Dosimeter Board Template

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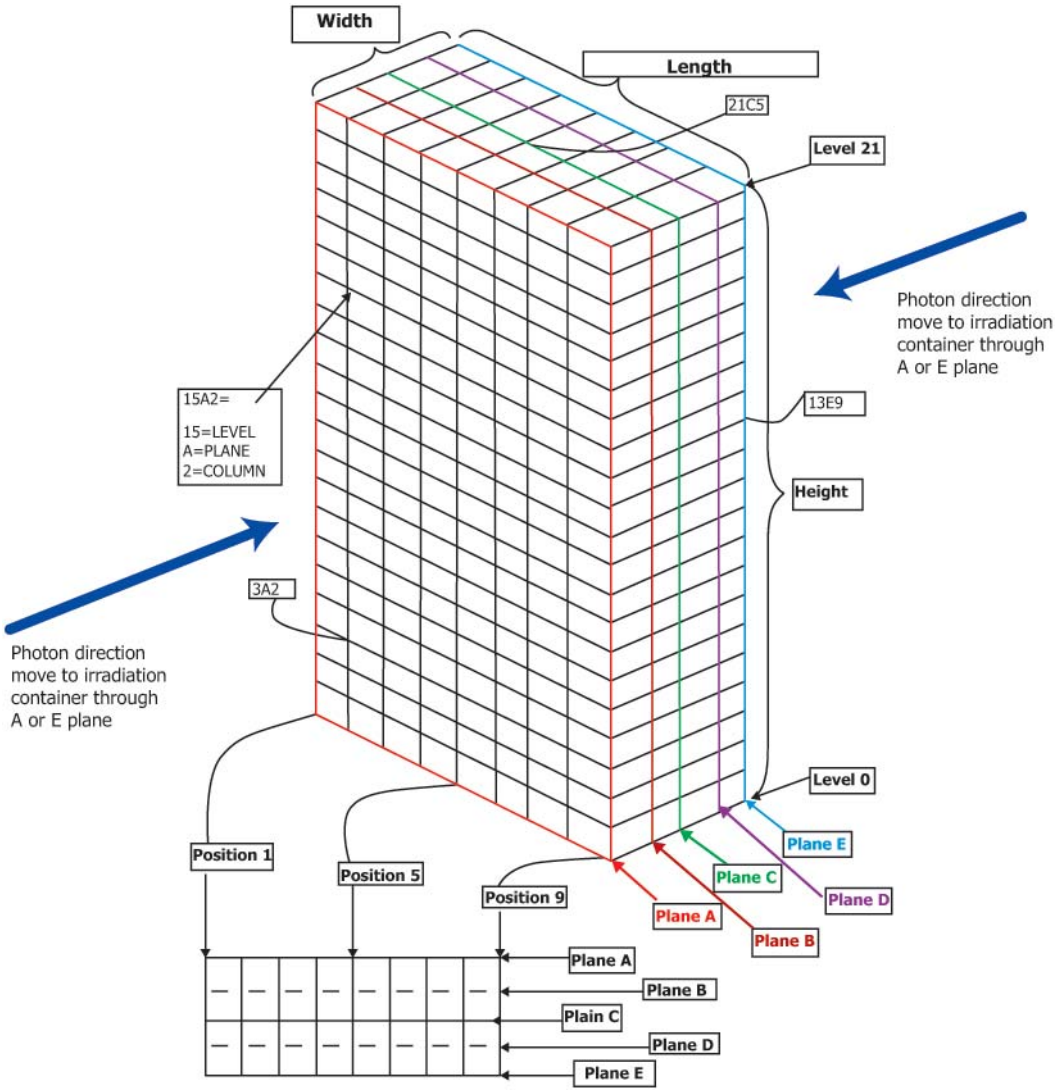

FIG. 2 Dosimeter Placement Array – 3D Grid as Viewed from the Load Station

loads to be dose mapped should be sufficient (as per Table 2) to determine the variability of dose.

9.2.8 Quiet system studies and trailing effects during transitioning should be considered as both conditions may exist at different times during processing. Additional ways to influence the absorbed-dose distribution include multiple source rack(s) or source rack position changes.

9.2.9 Dose mapping should be carried out over a range of selected operating parameters which cover the operational limits used in the irradiation of products.

9.2.10 A dosimeter labeling scheme should be developed to define the location of each dosimeter.

9.2.11 A template may be used to ensure dosimeter placement is consistent throughout the irradiation container as well as from one OQ test to the next. The dosimeter template may be used for any OQ tests that have replicate dosimeter placements. An example of a dosimeter template is shown in Fig. 1. The dosimeter placement template can apply to any type of dosimeter.

9.2.12 Adhere dosimeters to paperboard sheets or template, if used, in accordance with the applicable dosimeter grid. Place dosimeter sheets when loading the reference material in the respective irradiation container. Dosimeter strips or sheets may be used to increase the spatial resolution of the dose map.

9.2.13 In some cases, the dosimeter can be physically displaced within its packaging to ensure a more precise position. Although the Perspex dosimeter is illustrated in Fig. 1, the principle is applicable to other types of dosimeters. The illustrated sheet shows a horizontal template; a similar template can be assembled for a vertical plane. Following irradiation, confirm that the dosimeter position and dosimeter label are correct. Retrieve and measure each dosimeter. Ensure all dosimeters have been retrieved, and evaluate the data in accordance with the facility's procedures.

9.2.14 The use of temperature strips may be required depending on the impact of temperature on the dosimetry system in use. In addition, placing temperature strips at

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maximum dose/maximum dose rate locations will provide an estimate of irradiation temperature.

NOTE 2—The source rack is typically parallel to the "ACE" planes. Fig. 2 is typically known as the "ACE" coordinate system. The dosimeter coordinate is defined as Level-Plane-Column where 'level' refers to the height of the product or reference material above the bottom of the irradiation container (that is, Levels 0 to 21 as in Fig. 2). The 'Plane' refers to the width coordinate (that is, Planes A, C and E), and the 'column' is the length coordinate (that is, Positions 1, 3, 5, 7 and 9). For example, 15-A-2 refers to Level 15, Plane A and Column 2. In this example, the Levels, Planes and Positions are spaced at equal increments; however, based on the expected dose distribution, a facility may choose to include non-integer Levels (for example, Levels 0.5, 1.5 and 20.5) or even Positions (that is, Positions 2, 4, 6, or 8).

NOTE 3—The use of reduced-height loads, including the center-loading, may mean that the design of the OQ grid for these applications might be modified. Document the rationale for the OQ grid(s) used for these studies. For example, Level T may replace Level 21 and 'float' with the top of the process load. When the process load is reduced in height, Levels 19 and 20 may be eliminated in which case Level 18 becomes Level T. Similarly Planes A and E may be defined to compress with the process load width, and Positions 1 to 9 may also compress with the length of the process load.

NOTE 4—The spacing between dosimeters depends on the size and density of the materials, and the irradiator design. The OQ grid might not utilize all available dosimeter positions defined within a grid, but the dosimeter positions are chosen to ensure that the D_{min} and D_{max} zones are included. The use of mathematical modelling (Guide E2232), and results from irradiators of similar or identical design, and experience from the manufacturer and the experience and expertise of the facility staff can assist with the rationalization of the OQ grid.

NOTE 5—Note that Planes B and D are illustrated in Fig. 2. They are sometimes referred to as the 'quarter planes' and may contain an absolute or equivalent D_{min} zone. Mathematical modelling, other OQ results and irradiator knowledge may allow the facility to remove Planes B and D from the OQ grid.

9.3 *Off-carrier OQ Dose Mapping Study*—See Appendix X3.

9.3.1 The off-carrier radiation process utilizes available areas inside the radiation shield, but outside the irradiator pathway to irradiate materials.

NOTE 6—This OQ study will not be required if the facility does not utilize off-carrier processing. This OQ study may not be required if the facility employs a 100 % verification 'mini-map' strategy.

NOTE 7—For off-carrier and static irradiations, either the dosimetry system's calibration curve requires verification for conditions of use, or the calibration curve is derived under conditions of use. Refer to ISO/ASTM 51261.

9.3.2 Refer to Table 2 for details associated with the type of OQ grid to be used, and the minimum number of irradiation containers and the minimum number of densities for the OQ study.

9.3.3 Off-carrier OQ dose mapping data may not mimic routine irradiation conditions due to the impact of material density and level of fill of material for irradiation containers surrounding the source rack (for example, irradiation temperature and dose rate). Consideration should be given to whether irradiation of off-carrier materials will occur in a static (non-movement) or rotation condition. The placement of dosimeters for the dose mapping may be different depending on the irradiation condition. In general, off-carrier OQ dose mapping involves placement of dosimeters throughout the reference material.

9.3.4 A schematic of the irradiator with off-carrier locations should be produced showing the location of the off-carrier processing positions relative to the source rack, which may require physical measurements. Fig. 3 is an example of an off-carrier schematic.

NOTE 8—In Fig. 3, the source pass is illustrated as 'A.' Off-carrier positions are illustrated as 'B' and 'C.' The source racks are shown in blue.

9.4 *Static Source Pass OQ Dose Mapping Study*—See Appendix X4.

9.4.1 A static OQ dose mapping determines the measured dose and the relative percentage of dose distribution within each irradiation container dwell position within the source pass.

NOTE 9—The use of mathematical methods can be beneficial in the assessment of static dose mapping. See Guide E2232 for further guidance.

9.4.2 Information from static dose studies will be useful in irradiator scheduling, specifically in understanding the relative dose contribution at each dwell position to help determine cycle timer setting changes.

9.4.3 While advantageous for a facility to perform, this study is not necessary for normal operation, specifically if cycle time changes are not routinely performed.

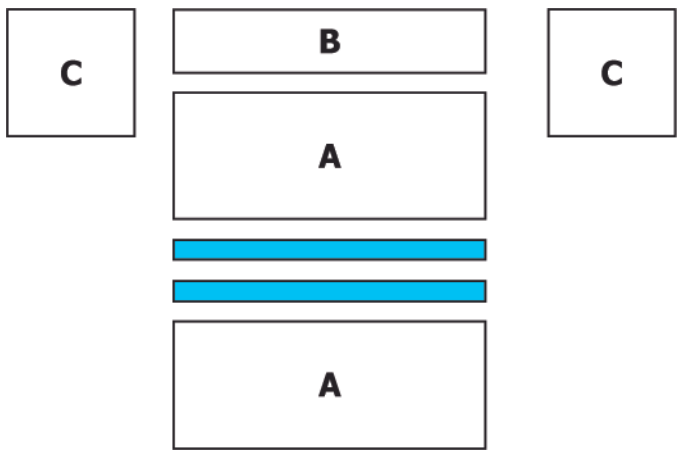

FIG. 3 Sample Schematic for Off-Carrier Processing Locations

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9.4.4 Information from static dose map studies can be used to estimate dose delivered due to deviations from routine processing conditions. Anomalies that impact the qualified state of the irradiator that result in a change in the intended time at dwell position(s) may result in dose delivered that cannot be quantified from routine OQ data.

9.4.5 If both sides of the source pass mirror each other, as confirmed via physical/dosimetric measurement, it may be possible to complete the static study using only one side of the irradiator.

9.4.6 Static tests may provide data that can support the dose estimate for these types of unplanned events:

9.4.6.1 A source rack does not move to the DOWN position when expected, and

9.4.6.2 An additional or skipped dwell cycle.

9.4.7 Refer to Table 2 for details associated with the type of OQ grid to be used, and the minimum number of irradiation containers and the minimum number of densities for the OQ study.

9.4.8 Move irradiation containers containing dosimeters to the defined dwell positions in the irradiator.

9.4.9 Set the control system timer to raise the source rack for the pre-determined time. Ensure the irradiation containers do not index during this OQ study.

9.4.9.1 The time selected should be sufficient to deliver dose to the minimum and maximum positions in the irradiation container within the calibrated range of the dosimetry system. However, there may be dwell positions that do not significantly contribute to the overall dose. It is still acceptable to place dosimeters in those locations since the outcome is to determine which dwell positions do not significantly contribute to the overall dose and are therefore less important in determining the impact on cycle time changes.

9.4.10 Results should be analyzed in order to provide information regarding dose at each dosimeter position as well as relative percent contribution by dwell position.

9.4.11 The use of mathematical modelling techniques (Guide E2232) can facilitate estimation of doses and dose rates at positions where dosimetry placement might be challenging.

9.5 *Cycle-Time Transition Dose Mapping OQ Study*—See Appendix X5.

9.5.1 The cycle-time transition study assesses the effect of cycle time (CT) changes on dose distribution within irradiation containers for shuffle-dwell irradiator systems.

9.5.2 This study is helpful for a facility when planning changes to CT during routine operation to ensure doses are within expectation. A facility may determine this study is unnecessary based on non-challenging routine dose requirements, or when products that are processed do not require significant changes to CT.

9.5.3 Refer to Table 2 for details associated with the type of OQ grid to be used, and the minimum number of irradiation containers and the minimum number of densities for the OQ study.

9.5.4 Determine the number of irradiation containers needed to fill the defined path.

9.5.5 Irradiation containers with dosimeters are placed such that when the cycle time change occurs, an irradiation container with dosimeters is located at the beginning of each irradiator pass. For example, in a four-pass, one-level source pass containing 16 dwell positions (with four irradiation positions per pass), the irradiation containers with dosimeters are represented by Positions #A, #B, #C and #D. Refer to Fig. X5.1.

NOTE 10—The impact of one CT change study (for example, -25 % CT change) may enable conclusions to be reached for other CT changes (for example, -5 %, +10 % CT changes).

9.5.6 Data collected from the CT change OQ study can be compared to the quiet system OQ studies. This analysis includes:

9.5.6.1 Location and magnitude of minimum and maximum doses,

9.5.6.2 Relative change in minimum and maximum doses as compared to the quiet system OQ study, and

9.5.6.3 Effect on adjustment factor relationships if using reference point monitoring.

9.5.7 Results should be able to provide information regarding dose at each dosimeter position, and the impact of CT change.

9.6 *Process Interruption Dose Mapping OQ Study*—See Appendix X6.

9.6.1 Process interruption OQ studies determine the absorbed-dose contribution to the process load when the radiation source moves from the down position (storage) to the up position (irradiation), and back to the down position.

9.6.2 Events that result in multiple process interruptions may not be captured by routine dosimeters. This OQ study allows the facility to determine the dose impact for one or more process interruptions. The location of the source rack and the source rack travel time for the process interruption study relative to the baseline process interrupt OQ test should be assessed.

9.6.3 The dose delivered and dose distribution during the process interruptions depend on:

9.6.3.1 the irradiation container location,

9.6.3.2 the total source activity and source distribution,

9.6.3.3 the number of source transitions,

9.6.3.4 the location of the irradiation containers, and

9.6.3.5 whether or not the irradiation container indexes between multiple process interruptions.

9.6.4 The data from a process interruption study may be used to estimate the additional dose delivered to an irradiation container for any event where the source rack is lowered and raised during an irradiation run.

9.6.5 There are limitations to the use of process interruption OQ data at a single density when applied to actual product with a different bulk density and load configuration. However, the change in dose on the front plane nearest the radiation source is expected to be representative for a range of product density and load configurations.

9.6.6 Since the dose contribution from process interruption typically occurs at locations closest to the source rack, the number of irradiation containers dose mapped can be reduced. The irradiation facility should document the location of all irradiation containers filled with reference material and dosimeters locations.

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9.6.7 Refer to Table 2 for details associated with the type of OQ grid to be used, and the minimum number of irradiation containers and the minimum number of densities for the OQ study.

9.6.8 Irradiation containers directly adjacent to the dose mapped containers should also be filled with the same reference material. The adjacent irradiation containers potentially shield the dose mapped irradiation containers.

9.6.9 Temperature strips may provide useful temperature information, depending on the impact of temperature on the dosimetry system.

9.6.10 There are a number of methods that can be utilized to assess the effect of process interruptions. Two methods are provided here.

9.6.11 *Process Interruption – OQ Study Method A:*

9.6.11.1 This method requires a sufficient number of process interrupts to ensure that the increase in dose can be measured relative to a known quiet system study.

9.6.11.2 The dose determined from the quiet system study is used as the baseline from which the process interruption irradiation container dose is determined (same target D_{min}). A pre-determined number of process interruptions are completed with the irradiation containers at the prescribed locations without indexing the irradiation containers. Following the completion of the process interruptions, all irradiation containers continue to cycle before exiting the irradiator.

9.6.11.3 The dose augmented during the source interruption should fall within the dosimetry system's calibration range.

9.6.11.4 Place dosimeters throughout the process load(s) as determined from Table 2. As a minimum, place dosimeters on the front plane that will be directly adjacent, and centered on the radiation source rack during the process interruption study.

9.6.11.5 With the source rack raised, move the irradiation containers to the desired positions within the irradiator. Use a cycle time that will achieve the desired minimum dose.

9.6.11.6 After the irradiation containers reach the desired positions, lower the radiation rack(s) to the storage position, and raise the source rack. Repeat this process the desired number of times, but ensure the irradiation containers do not index during the source rack movements.

9.6.11.7 After the desired number of source interrupts has occurred, the irradiation containers are allowed to index and exit the irradiator with the source racks raised.

9.6.12 *Process Interruption – OQ Study Method B:*

9.6.12.1 With this method, the transit dose contribution is measured directly and requires an adequately sensitive dosimeter (for example, Alanine, Fricke) that can measure the dose associated with only one process interruption (for example, <100 Gy) or with multiple interrupts as long as the accumulated dose falls within the dosimetry system's calibration range.

9.6.12.2 Place dosimeters throughout the process load(s). As a minimum, place dosimeters on the front plane that will be directly adjacent, and centered on the radiation source rack during the source interrupt study.

9.6.12.3 With the source rack in the down position, move the irradiation container(s) to the desired position(s) within the irradiator.

9.6.12.4 After the irradiation container(s) reach the desired position(s), raise the source rack(s) to the fully up position, and immediately lower the source rack(s) to the down position. With the source rack in the down position, the irradiation containers are indexed until they exit the irradiator.

9.6.13 Data collected from the source interrupt OQ study can be compared to the quiet system OQ studies. This analysis may include:

9.6.13.1 Location and magnitude of minimum and maximum doses,

9.6.13.2 Relative change in minimum and maximum doses as compared to the quiet system OQ study, and

9.6.13.3 Effect on adjustment factor relationships if using reference point monitoring.

9.6.14 Results should be able to provide information regarding dose at each dosimeter position, and the impact of process interruptions on the location and magnitude of D_{min} and D_{max}.

9.7 *Center-loading OQ Dose Mapping Study*—See Appendix X7.

9.7.1 Center loading OQ studies reduce the effective density of material, and may improve the dose uniformity.

9.7.2 Based on a review of product dose ranges and densities to be routinely processed, a facility may determine this OQ study does not need to be performed.

9.7.3 In addition, the center-loaded product may impact the dose distribution in the adjacent full irradiation container which should be determined.

9.7.4 Refer to Table 2 for details associated with the type of OQ grid to be used, and the minimum number of irradiation containers and the minimum number of densities for the OQ study.

9.7.5 Load the irradiation container with reference material. Stabilizing material can be used to ensure that the stack does not move during the OQ study. Alternately, stabilizing material may be used between selected layers to stabilize the load; for example, a sheet of corrugate with dimensions matching the footprint of the container may be placed at various layers of the center-loaded material.

9.7.6 In addition, it may be necessary to characterize the impact of center loading on an adjacent full irradiation container.

9.7.7 Data collected from the center-loaded OQ study can be compared to the quiet system OQ studies. This analysis includes:

9.7.7.1 Location and magnitude of minimum and maximum doses,

9.7.7.2 Relative change in minimum and maximum doses as compared to the quiet system OQ study, and

9.7.7.3 Effect on adjustment factor relationships if using reference point monitoring.

9.7.8 Results should be able to provide information regarding dose at each dosimeter position, and the impact of center loading.

9.7.9 These OQ studies assess the impact center-loaded irradiation containers on routine processing. The magnitude of impact may require restrictions or additional control measures to be placed on the allowance of center-loaded containers.

9.8 *Reduced Length OQ Study*—See Appendix X8.

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9.8.1 Product lot sizes and case carton sizes often result in loading configurations that do not fully utilize the available irradiation container volume.

9.8.2 A series of OQ dose maps may be performed at various stack lengths (keeping the height and width fixed) to determine how the dose magnitude and distribution changes when compared to OQ studies completed with product filled to design capacity.

9.8.3 It is useful to perform these studies in a similar fashion as the full design capacity OQ studies where homogenous material of a similar density is placed along with a defined dosimeter in order to detect changes in D_{min} and D_{max} magnitude and locations and DUR.

9.8.4 The reduced-length irradiation container dose distribution should be assessed, as well as the impact on the adjacent full irradiation container.

9.8.5 Refer to Table 2 for details associated with the type of OQ grid to be used, and the minimum number of irradiation containers and the minimum number of densities for the OQ study.

9.8.6 Load the irradiator with sufficient irradiation containers preceding and following the reduced stack length irradiation container. These irradiation containers are filled to the design limits with the same material.

9.8.7 Select a cycle timer setting based on a target minimum dose as determined by the irradiation facility.

9.8.8 Data collected from this OQ study can be compared to the quiet system OQ studies. This analysis includes:

9.8.8.1 Location and magnitude of minimum and maximum doses,

9.8.8.2 Relative change in minimum and maximum doses as compared to the quiet system OQ study, and

9.8.8.3 Effect on adjustment factor relationships if using reference point monitoring.

9.8.9 Results should be able to provide information regarding dose at each dosimeter position, and the impact of reduced length.

9.8.10 The aim of these assessments is to determine the likely impact varying levels of a reduced length irradiation container may have on routine processing. The magnitude of impact may require restrictions or additional control measures to be placed on the allowance of reduced length containers.

9.8.11 Some examples of possible impacts of reduced length containers are:

9.8.11.1 Invalidation of adjustment factors if using reference point monitoring leading to either an overestimation of minimum dose or underestimation of maximum dose.

9.8.11.2 Underestimation of maximum dose if using direct minimum and maximum monitoring practices due to reduced shielding effect, creating a maximum location near the ends of the process load.

9.8.12 Based on the potential impact of reduced length irradiation containers, some common industry practices for reducing the magnitude of this impact include:

9.8.12.1 Placement of additional dosimeters on reduced length irradiation containers in order to capture possible maximum doses.

9.8.12.2 Use of a removable shield might also be considered in order to reduce the impact on the maximum dose. However, its use may reduce the dose to product in nearby irradiation containers.

9.8.12.3 Process scheduler knowledge of reduced length irradiation containers is important in order to make necessary cycle time adjustments.

9.9 *Repeatability of Process Dose Through the Irradiator*—See Appendix X8.

9.9.1 The repeatability OQ exercise will assess components of variability related to the radiation source, variations in material, dosimeter placement and conveyor system, and will manifest itself in most OQ exercises. This repeatability OQ exercise is intended to isolate various sources that contribute to repeatability.

9.9.2 Place dosimeters at the defined D_{max} and D_{min} zones in the prescribed irradiation containers using one homogenous material density that is representative of actual processing. While providing useful information regarding variability of dose at key locations, a facility may decide that this study is of limited benefit based on: historic information on variability, information from similar irradiators regarding variability, or knowledge that this repeatability of dwell information will inherently be seen in routine operation (albeit it will contain additional sources of variability such as product variation, dosimeter placement variation).

9.9.3 The number of irradiation containers with dosimeters is important since the goal is to establish the dose variability of the radiation process. For example, in a pallet irradiator, dosimeters could be placed on every pallet. In a complex multi-level, multi-pass system, dosimeters placed in every second irradiation container may be adequate.

9.9.4 Placing temperature strips at different locations will provide an estimate of maximum temperature of the irradiator. Temperature may have an impact on both dosimetry and products being irradiated during routine processing. The maximum temperature reached during processing will vary depending on the dose and the irradiator path.

9.9.5 Calculate the relative standard deviation for the D_{min} and D_{max} for each pathway used and compare against the acceptance criteria (for example, 3 % or less).

9.10 *Transition Effects for Mixed-density Within the Irradiator*—See Appendix X9.

9.10.1 For irradiators operated in a continuous irradiation process, density may vary between process loads within the irradiator according to the schedule; the effect of changes in density within the irradiator during routine processing may be evaluated in this OQ. Certain irradiation facilities might not require transition studies depending on the density range of product processed.

9.10.2 The impact of density between process loads is also a factor for irradiators run in a batch process mode. The batch irradiation process involves processing irradiation containers of product in the irradiator without any irradiation containers exiting or entering the irradiator. However, different density irradiation containers can still influence the dose distribution in the adjacent irradiation containers.

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9.10.2.1 Like other irradiator designs, batch irradiators can consist of multiple rows of irradiation containers.

9.10.3 If such effects are present, they will be measurable between the radiation-absorption characteristics of the process load of the given production run and those of the process loads in the adjacent production runs.

9.10.4 This test consists of dose mapping exercises carried out to evaluate the effects on D_{min} and D_{max} magnitude and locations and Dose Uniformity Ratio (DUR) that may occur in the irradiation containers when such changes take place.

9.10.5 The acceptable range of densities that can be processed together will be determined based on these measurements.

9.10.6 To study the effect of surrounding process load on the D_{min} and D_{max} magnitude and locations and DUR, different configurations need to be tested according to irradiator design.

9.10.7 The data recorded for these containers are compared to the homogeneous dose mapping data for these materials to determine the additional dose variation, if any, when the two material densities are irradiated sequentially.

9.10.8 The number of irradiation containers to be dose mapped depends on the irradiator design and also on the routine process condition. Examples are given in Tables 1 and 2.

9.10.9 Dosimeters are placed at the minimum and maximum dose zone locations determined during the quiet system dose mapping (see 8.1).

9.10.10 Dose map results will be compared to the results of the test when products are surrounded by the same density, and identification of acceptable density mixes / density changes between successive runs may be arrived at using an appropriate method of analysis.

9.10.11 Data collected from this OQ study can be compared to the quiet system OQ studies. This analysis includes:

9.10.11.1 Location and magnitude of minimum and maximum doses;

9.10.11.2 Relative change in minimum and maximum doses as compared to the quiet system OQ study; and

9.10.11.3 Effect on adjustment factor relationships if using reference point monitoring.

9.10.12 Results should be able to provide information regarding dose at each dosimeter position, and the impact of mixed-density within the irradiator.

9.10.13 The results of the tests described in 9.10.11 may then be used as input to decision rules regarding mixing or changing densities during routine irradiations.

9.11 *Reduced Height Container Impact*—See Appendix X10 and Appendix X11.

9.11.1 Product lot sizes and case carton sizes do not always result in loading configurations that fully utilize the available product volume. Instances where the process load height does not reach the full capacity of the irradiation container can result in changes to dose distribution from conditions experienced when containers are filled to design capacity. Most commonly this will lead to an increase in expected doses near the top of the process load due to the absence of product to shield the top of the process load. Adequately characterizing this effect is necessary to determine the potential impact to routine process runs and possibly set requirements for minimum stack height or necessity of non-product shielding to be placed. Facilities that can ensure there are no reduced height irradiation containers, or who plan to use dummy materials/dunnage for any reduced height irradiation containers may not be required to determine the impact of non-existent reduced height irradiation containers.

9.11.2 The reduced height irradiation container may affect the dose distribution in the adjacent full irradiation containers. This effect should be determined.

9.11.3 A series of dose maps may be performed at various stack heights to determine how the dose distribution and magnitude transforms when compared to OQ studies completed with product filled to design capacity. Studies might be performed at varying densities and heights representative of product that is typically loaded into an irradiation container.

9.11.4 It is useful to perform these studies in a similar fashion as the full design capacity OQ studies where homogenous material of a similar density is placed along with a defined dosimeter in order to detect changes in D_{min} and D_{max} magnitude, locations, and DUR.

9.11.5 Load the irradiator with sufficient irradiation containers preceding and following the reduced stack irradiation container. These irradiation containers are filled to the design limits with the same material.

9.11.6 Select a cycle timer setting based on a target minimum dose as determined by the irradiation facility, taking into consideration the calibrated dose range of the dosimetry system in use.

9.11.7 Complete the irradiation and compile the data to determine the average dose at each position as well as standard deviations.

9.11.8 Data collected from this OQ study can be compared to the quiet system OQ studies. This analysis includes:

9.11.8.1 Location and magnitude of minimum and maximum doses;

9.11.8.2 Relative change in minimum and maximum doses as compared to the quiet system OQ study; and

9.11.8.3 Effect on adjustment factor relationships if using reference point monitoring.

9.11.9 Results should be able to provide information regarding dose at each dosimeter position, and the impact of reduced-height irradiation containers.

9.11.10 The aim of these assessments is to determine the likely impact varying levels of a reduced height irradiation container may have on routine processing. The magnitude of impact may require restrictions or additional control measures to be placed on the allowance of reduced height filled containers.

9.11.11 Some examples of possible impacts of reduced height containers are:

9.11.11.1 Invalidation of adjustment factors if using reference point monitoring leading to either an overestimation of minimum dose or underestimation of maximum. These situations can occur when the reference dosimeter is located in a near maximum dose zone, or near minimum dose zone, respectively.

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9.11.11.2 Underestimation of maximum dose if using direct minimum and maximum monitoring practices due to reduced shielding effect, creating a new maximum location near the top of the process load.

9.11.12 Based on the potential impact of reduced height irradiation containers, some common industry practices for reducing the magnitude of this impact include:

9.11.12.1 Requiring all containers to be filled a minimum fill level, either through product batch size changes or through the use of dunnage material to be placed on top of a reduced height irradiation container.

9.11.12.2 Placement of additional dosimeters on reduced height irradiation containers in order to capture possible maximum doses (for example, TA5, representing the top level of products, however high, in the A5 position).

9.11.12.3 Use of a removable shield might also be considered in order to reduce the impact on the maximum dose. However, its use may reduce the dose to product in nearby irradiation containers. The use of such a shield should be subject to dosimetric validation.

9.11.12.4 Process scheduler knowledge of reduced height irradiation containers is important in order to make necessary cycle time adjustments so as not to exceed maximum dose.

9.12 *Effects of Mixed-density Within an Irradiation Container*—See Appendix X12.

9.12.1 A mixed-density irradiation container is a container that contains material loaded to its design limit for length, width and height, but contains a mixture of reference material densities. Although some examples of a mixed-density study are given, it is recommended that an actual study reflects what mixed density might be processed under actual processing conditions.

9.12.2 This OQ test can quantify the change in D_{min} and D_{max} magnitudes and locations and DUR for facilities that will process actual product with mixed densities and determine which mixed density geometries might be acceptable for actual product.

9.12.2.1 The mix of densities should be representative of the actual mix of product that is expected under actual processing conditions. For example, the top half of irradiation container contains low density material, and the bottom half contains medium density material.

9.12.3 The mixed-density distribution is expected to have an impact on the dose magnitude and distribution. However, if the range of mixed densities that are utilized in actual processing is minimal, the impact on dose magnitude and distribution will be reduced.

9.12.4 The required number of irradiation containers and type of OQ grid are given in Table 2.

9.12.5 If such effects are present, they will be measurable between the radiation-absorption characteristics of the process load of the given production run and those of the process loads in the adjacent production runs.

9.12.6 This test consists of dose mapping exercises carried out to evaluate the effects on dose and DUR that may occur in the irradiation containers with mixed densities.

9.12.7 The acceptable range and distribution of mixed densities that can be processed together will be determined based on these measurements.

9.12.8 The effect of mixed density changes on D_{min} and D_{max} locations and DUR is determined by sequentially processing irradiation containers with mixed densities and by dose mapping the required number of irradiation containers in accordance with Table 2.

9.12.9 The data recorded for these containers are compared to the homogeneous dose mapping data for these materials to determine the additional dose variation, if any, when the two material densities are irradiated within the same irradiation container.

9.12.10 Dose map results will be compared to the results of the test when products are surrounded by the same density using methods described in the Appendixes.

9.12.11 According to the results of the study, a decision could be made for routine process procedure. Additional testing can be performed in order to determine the impact.

9.12.12 Data collected from this OQ study can be compared to the quiet system OQ studies. This analysis includes:

9.12.12.1 Location and magnitude of minimum and maximum doses,

9.12.12.2 Relative change in minimum and maximum doses as compared to the quiet system OQ study, and

9.12.12.3 Effect on adjustment factor relationships if using reference point monitoring.

9.12.13 Results should be able to provide information regarding dose at each dosimeter position, and the impact of mixed-density within the irradiation container.

10. Assessment of OQ Data

10.1 There are a number of tests that can be performed to determine if there has been any significant change in the dose distribution. An individual test should not be used in isolation of other tests as an indicator of significant change in the dose distribution. The tests used to determine equivalence should be summarized in facility procedures and assessed together to determine if there has been any significant change in dose distribution.

10.2 Facility procedures should be established for each test used. If the assessment fails to demonstrate dose distribution equivalence, additional OQ tests may be required (that is, full OQ testing), with a repeat of PQ. Ensure there is written justification for all decisions made.

10.3 *Dose Uniformity Ratio (DUR):*

10.3.1 For a defined minimum of irradiation containers, calculate the DUR for each density tested and compare with the baseline OQ study (typically the last full OQ baseline).

10.3.2 If the DUR is within the facility-defined confidence interval (for example, 95 % Confidence Interval (CI)) of the baseline OQ study, or when the facility-defined CIs overlap, it can be an indication that there has been no significant change to the DUR.

10.3.3 Determination of acceptable DUR by irradiator can be completed by assessing previous OQ dose maps. In Table 3, a 95 % CI is used in the acceptance evaluation. Table 3 uses one and two standard deviations. The guidance of the

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