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

Ionisation des aliments — Exigences pour l'élaboration, la validation et le contrôle de routine du procédé d'irradiation utilisant le rayonnement ionisant dans le traitement des aliments

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14470 was prepared by Technical Committee ISO/TC 34, *Food products*.

Introduction

Food irradiation is the process where food is exposed to ionizing radiation in order to improve its safety and quality. It is intended to be used only on food that has been produced under good manufacturing practice (GMP) principles. Many countries are using irradiation as a technological choice at some stage in food processing, making relevant the establishment of standards to assist customers, irradiator operators, and consumers.

The irradiation of food can be used for different purposes including control of pathogenic microorganisms and parasites, reduction of the number of spoilage microorganisms, inhibition of the sprouting of bulbs, tubers and root crops, extension of product shelf life or phytosanitary treatment.

When applicable, food irradiation should be incorporated as part of a food safety management system (ISO 22000). The irradiation of food is a critical control point (CCP) of a Hazard Analysis and Critical Control Points (HACCP) programme, contributing to the minimization of risks from the transmission of pathogenic microorganisms to consumers.

The main purposes of this International Standard are to:

a) provide requirements for the irradiation of food consistent with current standards and practices;

b) provide directions for a technical agreement between the customer and the irradiator operator;

c) establish a documentation system to support the controls on the food irradiation process.

To facilitate the application of this International Standard, it has been constructed in a form that can be used by internal and external parties, including certification bodies, for auditing an irradiator operator to assess its ability to fulfil all requirements for the irradiation of food.

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

1 Scope

This International Standard specifies requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food, and establishes guidelines for meeting the requirements.

NOTE 1 Requirements in this International Standard are consistent with those developed by the Codex Alimentarius Commission (CAC/RCP 19-1979, Rev. 2-2003[21], and CODEX STAN 106-1983, Rev. 1-2003[22]).

This International Standard covers irradiation processes using the radionuclides ^{60}Co or ^{137}Cs, electron beams or X-ray generators.

The requirements given in this International Standard are the minimum necessary to control the food irradiation process.

NOTE 2 The requirements can be addressed by a food safety management system (see ISO 22000).

This International Standard does not specify requirements for the primary production and/or harvesting, post-harvest treatment, storage and shipment, and packaging for foods that are to be irradiated. Only those aspects of the food production directly related to the irradiation process that may affect the safety or quality of the irradiated food are addressed.

This International Standard does not specify requirements for occupational safety associated with the design and operation of irradiation facilities.

This International Standard does not cover measuring or inspection devices that utilize ionizing radiation.

The application of this International Standard does not exempt the user from compliance with current and applicable legislation.

IMPORTANT Attention is drawn to regulatory and legal requirements that possibly exist for the irradiation and sale of irradiated food and the requirement for authorization to irradiate food.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 22000, *Food safety management systems — Requirements for any organization in the food chain*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
absorbed dose
quantity of ionizing radiation energy imparted per unit mass of a specified material

NOTE 1 The unit of absorbed dose is the gray (Gy) where 1 Gy is equivalent to the absorption of 1 J/kg.

NOTE 2 For the purposes of this International Standard, the term dose is used to mean “absorbed dose”.

[ISO 11137-1:2006[4], 3.1]

3.2
calibration
operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[ISO/IEC Guide 99:2007[16], 2.39]

3.3
correction
action to eliminate a detected non-conformity

NOTE A correction can be made in conjunction with a corrective action.

[ISO 9000:2005[2], 3.6.6]

3.4
corrective action
action to eliminate the cause of a detected non-conformity or other undesirable situation

NOTE 1 There can be more than one cause of non-conformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

NOTE 3 There is a distinction between correction and corrective action.

[ISO 9000:2005[2], 3.6.5]

3.5
cross-contamination
contamination of a material or of a product with another material or product

[ISO 15378:2011[7], 3.15]

NOTE Cross-contamination occurs when a product and/or raw material is contaminated directly or indirectly from another product and/or raw material through physical contact or the environment.

3.6
customer
organization or person that receives a product

[ISO 9000:2005[2], 3.3.5]

NOTE In the context of this International Standard, the “product” is irradiation treatment supplied by an irradiator operator under specified conditions.

3.7
dose distribution
spatial variation in absorbed dose throughout a defined region and material, integrated over a complete treatment

3.8
dose mapping
measurement of dose distribution and variability in material irradiated under defined conditions

[ISO 11137-1:2006[4], 3.10]

3.9
dose uniformity ratio
ratio of the maximum to the minimum absorbed dose

3.10
dosimeter
device having a reproducible, measurable response to radiation, which can be used to measure the absorbed dose in a given system

[ISO 11137-1:2006[4], 3.11]

3.11
dosimetry
measurement of absorbed dose by the use of dosimeters

[ISO 11137-1:2006[4], 3.12]

3.12
dosimetry system
interrelated elements used for determining absorbed dose, including dosimeters, instruments, associated reference standards and procedures for their use

[ISO 11137-3:2006[5], 3.1]

3.13
food irradiation
processing of food by ionizing radiation

3.14
food safety
concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use

[ISO 22000:2005, 3.1]

3.15
good manufacturing practice
GMP
combination of manufacturing and quality procedures aimed at ensuring that products are consistently manufactured to their specifications, and to avoid contamination of the product by internal or external sources

3.16
installation qualification
IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[ISO 11137-1:2006[4], 3.16]

3.17
irradiation container
holder in which product is transported through the irradiator

NOTE The holder can be a carrier, cart, tray, product carton, pallet or other container.

[ISO 11137-1:2006[4], 3.17]

3.18
irradiation facility
establishment where the irradiation process is performed

NOTE 1 Irradiation facilities can consist of an irradiator, shipping and receiving docks, storage zones for irradiated and non-irradiated food, conveyor system, safety systems and the infrastructure for personnel and facility services including record control (generation, updating, control and file).

NOTE 2 There are different types of irradiation facilities depending on the irradiator type, the conveyor system, the radiation source, the operating mode, among others.

3.19
irradiator
assembly that provides for safe and reliable irradiation processing, including the source of radiation, conveyor and source mechanisms, safety devices, and biological shield

3.20
irradiator operator
company or body responsible for irradiation of product

[ISO 11137-1:2006[4], 3.18]

3.21
non-conformity
non-fulfillment of a requirement

[ISO 9000:2005[2], 3.6.2]

3.22
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[ISO 11137-1:2006[4], 3.22]

3.23
performance qualification
PQ
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 its specification

[ISO 11137-1:2006[4], 3.23]

3.24
preventive action
action to eliminate the cause of a potential non-conformity or other undesirable potential situation

NOTE 1 There can be more than one cause for a potential non-conformity.

NOTE 2 Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

[ISO 9000:2005[2], 3.6.4]

3.25
process interruption
intentional or unintentional stoppage of the irradiation process

[ISO 11137-1:2006[4], 3.26]

3.26
process parameter
specified value for a process variable

NOTE 1 The specification for a food irradiation process includes the process parameters and their tolerances.

NOTE 2 Adapted from ISO 11137-1:2006[4], 3.27.

3.27
process variable
condition within a food irradiation process that changes or alters the process effectiveness

EXAMPLE Time, temperature, pressure, concentration, humidity, wavelength.

NOTE Adapted from ISO 11137-1:2006[4], 3.28.

3.28
product realization
all the steps involved, from conception to delivery of product

3.29
radiation-sensitive indicator
material which may be affixed to or printed on the product and which undergoes a visual change when exposed to ionizing radiation

NOTE Adapted from ISO/ASTM 51539:2005[11], 3.1.4.

3.30
radiation source
apparatus or material emitting or capable of emitting ionizing radiation

[ISO 921:1997[1], 964]

3.31
radionuclide
natural or synthetically produced unstable nucleus of an atom that emits ionizing radiation

[ISO 15190:2003[6], 3.19]

EXAMPLE Cobalt-60 or Cesium-137.

3.32
requalification
repetition of part of validation for the purpose of confirming the continued acceptability of a specified process

[ISO 11137-1:2006[4], 3.32]

3.33
transit dose
dose absorbed during travel of product or source to or from the non-irradiation to the irradiation position

[ISO 11137-1:2006[4], 3.45]

3.34
uncertainty of measurement
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[ISO/IEC Guide 99:2007[16], 2.26]

3.35
validation
documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

[ISO 11137-1:2006[4], 3.47]

4 Controlling the food irradiation process

4.1 Responsibility and authority

The responsibility and authority for implementing and performing the procedures described in this International Standard shall be specified, documented and communicated within the organization.

If the requirements of this International Standard are undertaken by different organizations (irradiator operator and customer) the responsibilities and authorities of each party shall be specified in a technical agreement.

NOTE The technical agreement might be established even when both parties are bodies of the same company.

4.2 Product realization

The following requirements for product realization, purchasing, traceability and calibration of monitoring and measuring devices shall be met from the determination of customer requirements.

a) Procedures for purchasing of products and services received from outside the organization shall be specified.

b) Procedures for identification and traceability of product shall be specified.

c) Procedures for calibration of all equipment, including dosimetry systems and instrumentation for test purposes, shall be specified. These procedures shall comply with the applicable clauses of ISO 10012, shall ensure measurement traceability to national or international standards and shall have a known level of uncertainty.

NOTE Guidance on the calibration of dosimeters can be found in ISO 11137-3[5] and ISO/ASTM 51261[9].

4.3 Monitoring, measurement and analysis

Appropriate methods for monitoring, measurement and analysis of the process shall be applied by the irradiator operator.

Procedures for control of products designated as non-conforming and for correction, corrective and preventive actions shall be specified and documented.

4.4 Technical agreement

A written agreement between the irradiator operator and the customer shall be specified, containing as a minimum but not limited to the following:

a) responsibilities of parties (see 4.1);

b) product specifications (see 6.2) — it is advisable that the irradiator operator have a system to periodically evaluate whether the customer is fulfilling the agreed conditions for the products to be irradiated;

c) process specifications (see 7.2);

d) assessment of change (see 12.6) — the customer should periodically audit the process to ensure that changes are duly assessed.

e) general documents and records required (see 10.7);

f) other considerations.

NOTE Other considerations include, among others:

— agreement on non-conforming irradiated products management (see 4.3);

— actions to be taken by each party when information is required by external authorities;

— periodic revision of the technical agreement;

— privacy clause.

4.5 Documentation

Procedures for each phase of the ionizing radiation process, such as technical agreement, development, validation, routine control and product release, shall be specified.

Documents and records required by this International Standard shall be reviewed and approved by designated personnel.

5 Irradiation facilities

5.1 Design

The design of the facilities shall be specified.

In order to prevent contamination and cross-contamination, necessary measures shall be taken to avoid direct or indirect contact of the food with potential sources of contamination.

The irradiation facilities shall be designed to irradiate food in accordance with irradiation process specifications and regulatory requirements.

5.2 Radiation sources

The type of radiation used shall be specified and in the case of X-rays or electron beam radiation, the energy of radiation shall also be specified.

NOTE The Codex Alimentarius Commission, as well as regulations in some countries, currently limits the maximum electron energy and nominal X-ray energy for the purpose of food irradiation.

5.3 Equipment

5.3.1 The irradiator and its method of operation shall be specified. The irradiator specification shall be revised as necessary and retained for the life of the irradiator.

Software used to control and/or monitor the process shall be prepared in accordance with a quality management system that provides documented evidence that the software meets its design intention.

5.3.2 For all radiation sources, the specifications shall at least describe:

a) the irradiator and its characteristics;

b) the premises, including the location of the irradiator;

c) the means provided for the segregation of non-irradiated product from irradiated product;

d) the construction and operation of any associated conveyor system;

e) the conveyor path(s) and the range of conveyor speed;

f) the dimensions, materials and construction of the irradiator container(s);

g) the manner of operation and maintenance of the irradiator and any associated conveyor system.

5.3.3 For gamma irradiators, specifications shall also describe:

a) the activity, type of radionuclide, and geometry of the gamma source;

b) the means of indicating the position of the gamma source;

c) the means of automatically returning the gamma source to the storage position and automatically ceasing conveyor movement if the process control timer or the conveyor system fails;

d) the means of returning the gamma source to the storage position, and automatically ceasing conveyor movement or identifying affected product if the gamma source is not at its intended position.

5.3.4 For electron beam and X-ray irradiators, specifications shall also describe:

a) the characteristics of the beam (electron or X-ray energy, and if applicable average beam current, scan width and scan uniformity);

b) for X-ray irradiators, the dimensions, materials and construction of the X-ray converter;

c) the means of indicating that the beam and the conveyor system are operating;

d) the means of ceasing irradiation if any failure of the conveyor occurs which affects the dose and product requirements;

e) the means of ceasing conveyor movement or identifying affected product if any fault in the beam occurs.

5.4 Personnel

The personnel at an irradiation facility shall comply with the applicable regulatory requirements and shall be competent on the basis of appropriate education, training, skills and experience.

The irradiator operator shall:

a) determine the necessary competence for personnel performing work affecting the good processing and hygienic practices for food irradiation;

b) provide periodic training or take other actions to satisfy these needs;

c) evaluate the effectiveness of the actions taken;

d) ensure that its personnel are aware of the relevance and importance of their activities;

e) maintain appropriate records of education, training, skills and experience.

6 Product

6.1 Product definition

The product to be irradiated shall be defined.

The food shall be packaged in suitable materials for each type of product and for their use in the irradiation process. When appropriate, these shall provide an effective barrier in order to avoid contamination or infestation after irradiation. (See also A.2.)

Any change to the defined product, its package or the presentation to the irradiation source, shall be documented and assessed for effect on the appropriateness of the irradiation process.

6.2 Product specification

The product specification shall include:

a) information and means necessary to identify the product to be irradiated (e.g. name and brief description);

b) purpose of the irradiation process (e.g. pathogenic control, shelf life extension, phytosanitary treatment);

c) packaging (materials; mass, shape and dimensions; orientation of the product within the package, if relevant), taking into account planned processing (including irradiation) and being consistent with any regulatory requirement (see, for example, ASTM F1640[20], and 21CFR179.45[24]);

d) dose specification (e.g. minimum and maximum dose requirements).

7 Process

7.1 Process definition — Dose range

The sensitivity of food to irradiation varies with the type of product, the packaging atmosphere, the product temperature during irradiation, and other factors.

The technically advisable dose range shall be specified and determined on the basis of knowledge of the effects of radiation on the product and its packaging and applicable regulatory requirements.

In those cases where the process dose range has to be determined experimentally, the approach shall be in accordance with the following considerations:

a) to ensure that the application of the process complies with applicable regulatory requirements;

b) to establish a clear statement of the technical objective(s) of the process;

c) to estimate the dose range to be applied to achieve the technical objective(s) based on scientific knowledge of the product;

d) to demonstrate that irradiation of test samples has been carried out to confirm that the estimated dose range can be met under practical production conditions;

e) to ensure that it is possible to meet the technical requirements, i.e. dose range and effectiveness of treatment, under practical production conditions;

f) to establish the process parameters under practical production conditions.

NOTE Published dose ranges for various foods can be found in documents prepared by the FAO/IAEA [32].

7.2 Process specification

The process specification shall include:

a) handling and storage conditions required (e.g. temperature conditions in the case of refrigerated or frozen foods), and a clear statement that the product shall be segregated from other products to avoid potential effects on product quality (e.g. undesirable aroma, contamination with substances from other products);

b) dosimetry system, agreed dose range, type and amount of dosimeters per batch, dose mapping, measurement equipment with a calibration programme;

c) process parameters records (see 9.4 and 10.7);

d) irradiation labelling requirements (e.g. radiation-sensitive indicators, Radura logo);

e) clear statement that the process shall be performed according to good irradiation practices.

8 Dosimetry

Dosimetry shall be performed to ensure that the specified absorbed dose is applied in each food irradiation application. The absorbed dose shall be measured using dosimetry systems that have been developed for this purpose.

Dosimetry shall be performed to characterize the radiation facility in operational qualification (OQ). Dosimetry shall be performed to measure dose distribution in irradiated products in performance qualification (PQ). Routine dosimetry shall be performed during product processing to monitor the irradiation process.

The selection and use of specific dosimetry systems in a given application shall be justified taking into account the dose range, radiation type, effect of influence quantities, required level of uncertainty, and required spatial resolution (see A.3).

9 Validation

9.1 Installation qualification (IQ)

The purpose of an installation qualification (IQ) programme is to demonstrate that the irradiator with its associated processing equipment and measurement instruments have been delivered and installed in accordance with their specifications. IQ includes documentation of the irradiator and the associated processing equipment and measurement instruments, establishment of the testing, operation and calibration procedures for their use, and verification that they operate according to their specifications.

Any modifications made to the irradiator during installation shall be documented.

For gamma irradiators, the activity of the source and a description of the location of individual components of the source shall be recorded.

For electron beam irradiators, the characteristics of the beam (electron energy, average beam current and, if applicable, scan width and scan uniformity) shall be determined and recorded.

For X-ray irradiators, the characteristics of the beam (electron or X-ray energy, average beam current and, if applicable, scan width and scan uniformity) shall be determined and recorded.

NOTE Methods for e-beam and X-ray characterization can be found in ISO/ASTM 51649[13] and ISO/ASTM 51608[12].

9.2 Operational qualification (OQ)

The purpose of operational qualification (OQ) of an irradiation facility is to establish baseline data for evaluating facility effectiveness, predictability, and reproducibility for the range of conditions of operation for each set of irradiator parameters and process parameters expected to be used for irradiating product. The dose absorbed by any portion of a product in an irradiation container depends on both the irradiator parameters and the process parameters. OQ is carried out by irradiating appropriate test materials to demonstrate the capability of the equipment to fulfil process definition.

a) Examples of irradiator parameters are the activity of the source of radiation, the source geometry, the source-to-product distance, the irradiation geometry, and the irradiator pathways (e.g. one- or two-sided irradiation, multiple passes).

b) Examples of process parameters are the length of time that a product is irradiated, the conveyor speed, the product composition and density, and the product-loading configuration.

Operating procedures for the irradiator and associated conveyor systems shall be specified.

Process and ancillary equipment, including associated software, shall be tested to verify operation to design specifications. The test method(s) shall be documented and the results shall be recorded.

Prior to OQ, the calibration of all instrumentation, including test instrumentation used for monitoring, controlling, indicating or recording, shall be verified.

OQ shall be carried out by irradiating homogeneous materials to be processed to demonstrate the capability of the equipment to deliver the specified dose range. OQ shall demonstrate that the irradiator, as installed, is capable of operating and delivering appropriate doses within defined acceptance criteria.

Dose mapping shall be carried out to characterize the irradiator regarding dose distribution and variability.

NOTE 1 Guidance on dose mapping is given in ISO 11137-3[5] and ASTM E2303[17].

NOTE 2 It is possible that the procedures for dose mapping outlined in this subclause are not feasible for some types of bulk-flow irradiators. In such cases, minimum and maximum doses can be estimated by using an appropriate number of dosimeters mixed randomly with and carried by the product through the irradiation zone. A sufficient number of dosimeters is necessary to obtain statistically significant results.

Dose mapping shall be carried out by a three-dimensional placement of dosimeter sets on the product within an irradiation container holding homogeneous material. The amount of homogeneous material in this irradiation container should be the amount expected during typical production runs or should be the maximum design volume for the irradiation container.

Placement patterns shall be selected to identify the locations of the maximum and minimum doses. More dosimeter sets shall be placed in these locations and fewer dosimeter sets in locations likely to receive intermediate doses.

Dose mapping shall be carried out in a sufficient number of irradiation containers to allow the estimation of the variability of the magnitude and distribution of the dose.

The number of loaded irradiation containers preceding and following the dose-mapped irradiation containers shall be sufficient to effectively simulate an irradiator filled with homogeneous product.

NOTE 3 Dosimetry data from previously qualified irradiators of the same design or calculations using mathematical models can provide useful information for determining the number and location of dosimeters and the number of irradiation containers for this qualification process.

If there is more than one conveyor path or more than one product configuration, dose mapping shall be carried out for each path and for each product configuration to be used for processing product.

NOTE 4 When products of different densities are in the irradiator at the same time, the dose distribution in any one product can be influenced by the different attenuation and scattering properties of the other products. The magnitude of these effects can be estimated by dose mapping of the first and last irradiation containers of two sequential production runs for homogeneous products of different densities.

The effect of a process interruption on dose and dose distribution shall be determined and recorded. The type of process interruption shall be described.

Dose-mapping records shall include a description of irradiation containers, irradiator operating conditions, used materials, dose measurements, and conclusions drawn.

For gamma irradiators, the relationship between the timer setting, conveyor speed, and dose shall be established.

For electron beam and X-ray irradiators, variations in the beam characteristics during dose mapping shall be within the limits of the irradiator specification.

For electron beam and X-ray irradiators, the relationship between the beam characteristics, the conveyor speed, and dose shall be established for each product configuration used for processing.

9.3 Performance qualification (PQ)

Dose limits are almost always determined by food irradiation applications. For a given application, one or both of these limits may be prescribed by government regulations. Dosimetry is used in PQ to determine the appropriate process parameters (including timer setting, conveyor speed, and product-loading configuration) for ensuring that the dose requirements for a particular product can be satisfied. This is accomplished by dose mapping of irradiation containers with specific product and product-loading configurations. The purpose

of the mapping is to determine the magnitudes and locations of the minimum and maximum doses and their relationships to the doses at locations used for monitoring during routine product processing.

A loading configuration within the irradiation containers shall be established for each product. The documentation for this loading configuration shall include specifications for parameters that determine the homogeneity of the loaded irradiation container and thus influence the dose distribution.

NOTE 1 Examples of such parameters include product size, mass, density, and orientation with respect to the radiation source. The size, shape, density, and loading configuration of the product in the irradiation container is determined primarily by considering the design parameters of the irradiation facility.

Locations of the regions of minimum and maximum dose for the selected product-loading configuration and routine process pathway shall be established. Product dose mapping shall be carried out for each processing pathway.

NOTE 2 Product dose mapping is accomplished by placing dosimeter sets throughout the volume of interest in one or more irradiation containers. Placement patterns to identify the locations of the dose extremes can be determined using data obtained from the dose-mapping studies during OQ or from theoretical calculations (e.g. mathematical modeling). Dosimeters are concentrated in the expected regions of minimum and maximum dose, while fewer dosimeters are placed in areas likely to receive intermediate dose.

NOTE 3 Different types of dosimeters can be used for the mapping procedure and for routine dose monitoring. In an irradiation container holding product with voids or non-uniform product, dosimeter sets are placed at locations where variations in composition or density can affect the regions of maximum or minimum dose. Dosimeter films in sheets or strips can also be employed to obtain useful information.

The variations in dose shall be determined by mapping the dose distribution in several irradiation containers with the same product-loading configuration and irradiation conditions.

NOTE 4 Variations in the doses measured in similar locations in different irradiation containers are possible when dose mapping a specific product-loading configuration. To determine the variations in dose, dosimeters are placed in several irradiation containers at the expected regions of the minimum and maximum doses. The variations in the measured dose values reflect the influence of, for example, the product-loading configuration (due to shifts in the contents of the irradiation container during its movement through the irradiator), the density of the product within the irradiation container, fluctuations in process parameters, and the uncertainties in the dosimetry system.

For gamma and X-ray irradiators, dose mapping shall be carried out to identify product that can be processed with the product being mapped. The effect on dose to product of different densities present in the irradiator shall be determined to define product that can be processed together.

If the locations of dose extremes identified during the product dose-mapping procedure are not readily accessible during production runs, alternative positions may be used for dose monitoring during routine product processing. The relationships between the doses at these alternative reference positions and the maximum and minimum doses shall be reproducible, established and documented.

Dose-mapping records shall include a description of the product, loading pattern, conveyor path, irradiator operating conditions, measurements of dose and conclusions drawn.

If the product dose-mapping procedure reveals that the dose uniformity ratio for the product is unacceptably large, appropriate measures shall be taken to reduce the ratio to an acceptable value.

NOTE 5 Methods of improving dose uniformity include re-arranging source elements, using attenuators or compensating dummies, irradiating from several sides, rotating the irradiation container during irradiation, and increasing source-to-product distance. In the case of bulk-flow irradiators, dose uniformity can be improved by arranging baffles to control product flow through the irradiation zone. A change of the product-loading configuration in an irradiation container can help to achieve the acceptable dose uniformity ratio.

The product dose mapping shall be repeated if changes are made, either in the facility or operation mode that could affect the magnitudes or locations of the maximum and minimum doses. The dosimetry data obtained during OQ following the change may serve as a guide in determining the extent of these dose-mapping studies.

NOTE 6 For chilled or frozen foods, product dose mapping can be performed with simulated product at room temperature. This requires that there be no change in any parameter (other than temperature) that could affect the dose during processing of the chilled or frozen food. Mapping of the simulated product includes placement of one or more dosimeters at a reference position known to be insulated from temperature changes during processing. During routine processing of the chilled or frozen product, dosimeters are placed at this reference position.

When required, the temperature of the food during irradiation shall be maintained within a specified temperature range (e.g. by using insulated containers).

NOTE 7 Dose mapping with a food is usefully performed at the temperature to which the food is chilled or frozen during actual product processing, using a dosimetry system that can be characterized at the intended processing temperature.

NOTE 8 It is possible that product dose mapping is not feasible for products flowing in bulk through the irradiation zone. In this case, minimum and maximum doses can be estimated by using an appropriate number of dosimeters mixed randomly with and carried by the product through the irradiation zone. A sufficient number of dosimeters is necessary to obtain statistically significant results. Theoretical modeling of the maximum and minimum doses can provide additional information.

9.4 Review and approval of validation

Information generated during IQ, OQ and PQ shall be reviewed. The outcome of the review shall be recorded.

From a consideration of the information and its review, a process specification shall be prepared and documented for each product.

Those documents shall include:

a) a description of the packaged product, including dimensions, density and orientation of product within the package and acceptable variations;

b) the loading pattern of product within the irradiation container;

c) the irradiator operating conditions and limits (i.e. beam characteristics and conveyor speed);

d) the conveyor path(s) to be used;

e) the dose range;

f) the routine dosimeter monitoring position(s);

g) the relationship between the dose at the monitoring position(s) and the minimum and maximum doses;

h) for a product that is to be given multiple exposures to the radiation field, identification of any special requirements (e.g. re-orientation or time restrictions) needed between exposures.

10 Routine monitoring and control

Prior to processing, any specific periodic tests, calibrations, maintenance tasks, and necessary requalification shall have been performed and outcomes recorded.

Procedures for product handling and maintaining product integrity before, during, and after irradiation shall be specified.

10.1 Process parameters

Process parameters (e.g. irradiation time, conveyor speed, product-loading configuration), shall be set, controlled, monitored, and documented, taking into account variations in the irradiator and uncertainty in

routine dosimetry, to ensure that the product is processed within specifications. If process parameters deviate outside prescribed processing limits, appropriate actions shall be taken.

10.2 Product-loading configuration

Products shall be loaded into the irradiation container according to the process specification. The effect on the dose distribution of changes or variations in the product-loading configuration shall be assessed.

The effects of changes in product densities or partially filled containers shall be assessed.

For irradiation containers containing fewer products than specified in the product-loading configuration, dose-mapping data shall exist, to confirm that the doses are within the specified limits. If dose-mapping data are not available, the dose-mapping procedure shall be performed to ensure that the dose distributions are adequately assessed.

10.3 Routine dosimetry

Dosimetry systems suitable for use in routine dosimetry are described in ASTM E2628[18].

10.3.1 Dosimeter location

Dosimeter(s) shall be placed, on the product within the irradiation container, at the predetermined maximum and minimum dose positions, or at a qualified reference dose location.

10.3.2 Placement frequency

The frequency of dosimeter placement shall be sufficient to verify that the process is in control. The frequency and its rationale shall be specified.

NOTE More frequent placement of dosimeters during the production run could result in less product rejection, should some operational uncertainty or failure arise.

10.4 Processing inventory control

Systems for quantifying product and maintaining product inventory shall be implemented throughout product receipt, loading, unloading, handling and release. Any discrepancies in the inventory shall be resolved before processing and/or release.

Incoming products shall be logged and given a code related to the customer lot identification in order to identify them at each step in their path through the irradiation facility. Facility design and administrative procedures shall ensure that irradiated and non-irradiated products are segregated. A radiation-sensitive indicator (e.g. a colour change indicator label) may be affixed on each package.

Products shall be stored under appropriate conditions. If products require special storage conditions (e.g. temperature requirements), adequate calibrated monitoring equipment shall be used to ensure that proper segregation means are implemented.

10.5 Labelling

The appropriate national and international requirements for the labelling of irradiated food shall be applied.

IMPORTANT To allow consumers and food processors to choose between irradiated and non-irradiated products, many governments have adopted labelling requirements. Labelling identifies the product as irradiated and can inform the consumer of the purpose and benefits of the treatment as well as handling or storage requirements. Labelling requirements differ among different national authorities. Users should always contact such authorities before designing labels. Many countries have adopted the internationally recognized "Radura-logo" as a means of labelling (see Figure 1). In some countries a statement, such as "Treated with radiation", "Treated by irradiation", or "Treated with ionizing energy", has to accompany the logo or can be used instead of the logo.

Figure 1 — International food irradiation logotype

10.6 Process interruptions

If process interruption(s) and/or process deviation(s) occur, they shall be recorded, together with the actions and/or corrective actions taken.

10.7 Irradiation process records

Irradiator operators shall maintain adequate records identifying the product, the applied process, the personnel responsible for the operation, the code assigned to the incoming products, the dosimetry results, including the type of dosimeters used, and the irradiation date. Any other data which might be of interest may also be recorded.

All records shall be available on request to competent authorities, the customer and other parties having a legitimate need for access to the information, and shall be kept for the time period specified in the technical agreement, which shall never be less than that specified in the current legislation.

11 Product release from irradiation process

Procedures for product release from irradiation shall be specified. The procedure(s) shall define the requirements for designating an irradiation process as conforming, taking into account the uncertainty of the measurement system(s). If these requirements are not met, irradiated product shall be considered as non-conforming.

The controls and related responsibilities and authorities for dealing with non-conforming irradiated product shall be specified.

Moreover, the management of non-conforming product shall be agreed between the irradiator operator and the customer and defined in the technical agreement. Documented procedures and records shall be maintained to eliminate problems and the causes of the non-conformities.

Radiation-sensitive indicators shall not be used as a proof of satisfactory radiation processing or as the sole means of differentiating irradiated products from non-irradiated products.

12 Maintaining process effectiveness

12.1 Demonstration of continued effectiveness

Initial critical factors shall be defined according to the purpose of the irradiation process.

NOTE In the case of controlling pathogenic or spoilage microorganisms, the critical factors are mainly associated with the number and radiation sensitivity of microorganisms present on the product; in the case of tuber and root crops sprouting, the critical factors are mainly related to post-harvesting conditions, among others.

These initial critical factors shall be monitored periodically in order to ensure that process is still effective to achieve the technical objective of the irradiation process.

12.2 Equipment calibration

Procedures for calibrating the measurements instruments and for checking their performance periodically to ensure that the instruments are functioning according to performance specifications, shall be established and implemented. The calibrations shall be traceable to national or international standards.

A performance check shall be made following any modification or servicing of the instruments.

12.3 Recalibration

The original calibration of the instrumentation used to control, indicate or record the irradiation process shall be verified at defined intervals.

12.4 Maintenance of equipment

A maintenance plan (including preventive actions), maintenance procedures and records shall be reviewed at specified intervals by a designated person and the results of the review shall be documented.

Equipment shall not be used to process product until all specified maintenance tasks have been satisfactorily completed and recorded.

12.5 Requalification of the irradiation process

Requalification of the irradiation process shall be carried out for defined product and specified equipment; it shall be performed at defined intervals and after the assessment of any change. The extent to which requalification is carried out shall be justified.

Requalification procedures shall be specified and records of requalification retained.

Requalification data shall be reviewed against specified acceptance criteria in accordance with documented procedures. Records shall be retained of reviews of requalification data, together with corrections made and corrective actions taken when the specified acceptance criteria are not met.

12.6 Assessment of change

Any change in the irradiator which could affect dose or dose distribution shall be assessed. If one or both of these is judged to be affected, then a requalification of part or all of IQ, OQ, and PQ shall be carried out.

Any change to the specified product, its package or the presentation for irradiation shall be documented and assessed for effect on the appropriateness of the irradiation process. Those parts of process definition or PQ that have to be undertaken shall be determined based on the nature of the change.

The outcome of the assessment, including the rationale for decisions reached, shall be recorded.

Annex A
(informative)

Guidelines

A.1 Design of food irradiation facilities

Irradiation facilities consist of an irradiator, temperature controlled storage zones for irradiated and non-irradiated products (under ambient, refrigerated and/or freezing conditions), conveyor system, safety systems and the infrastructure for staff and facility services including record control (generation, updating, control and file).

There are different types of irradiation facilities depending on the irradiator type, the conveyor system, the radiation source and operating mode, among others.

Food processing facilities can be categorized by irradiator type (e.g. container, bulk flow), conveyor system (e.g. shuffle-dwell, continuous), and operating mode (e.g. batch, continuous). Products can be moved to the location in the facility where the irradiation takes place, either while the source is fully shielded (batch operation) or while the source is in irradiating position (continuous operation). Products may be transported past the source at a uniform and controlled speed (continuous conveyance), or may instead undergo a series of discrete controlled movements separated by controlled time periods during which the irradiation container is stationary (shuffle-dwell). Irradiation containers generally make one or more passes on each side of the source. Irradiation containers may move past the source in a configuration in which the source either extends above and below the irradiation container (source overlap) or the irradiation container extends above and below the source (product overlap). In the latter configuration, the irradiation container is usually moved past the source at two or more levels. In bulk-flow irradiators, products such as grain or flour flow loosely past the source.

The segregation of irradiated from non-irradiated food can be accomplished by a controlled single direction movement of the food or food products through the facility and/or by separated storage areas.

The operator is advised to consult with the supplier of the irradiator equipment regarding the types of foods that the facility may process (if known) when discussing the irradiator's specifications. Details such as the packaging and regulatory limits of doses also assist in the design process. These design user requirements should be documented.

The irradiator design and the source-to-product geometry affect the delivery of dose to the product and therefore, the dose uniformity in the product within an irradiation container.

For economic and technical reasons (among others, maintaining product quality), various techniques are used to minimize the dose uniformity ratio in the product within an irradiation container.

A.2 Product definition

The size, shape and mass of the packages used for irradiation are specified in accordance with the type of product and the operating characteristics of the irradiator. Using product packages that are geometrically well defined and uniformly loaded can often optimize the dose distribution in the product within an irradiation container. With certain irradiation facilities, it may be necessary to limit the use of particular package shapes and sizes depending on the density of the product and facility operational qualification (OQ) data.

A.3 Dosimetry

Dosimetry is a major component of a total quality assurance programme for adherence to GMPs used in the production of safe irradiated food. CAC/RCP 19-1979, Rev. 2-2003[21] and CODEX STAN 106-1983, Rev. 1-2003[22] strongly emphasize the role of dosimetry for ensuring that the irradiation is properly performed.

The purpose of dosimetry is to ensure that the dose requirements for each food are met.

Influence quantities, such as irradiation temperature, need to be taken into account when calibrating dosimetry systems. See ASTM E2701[19], ISO/ASTM 51261[9] and ISO 11137-3[5] for further information.

ISO/ASTM 51707[15] describes the components of uncertainty in the measurement of absorbed dose and methods for estimating their values.

Dosimetry requirements and guidance for validation and operation of irradiation facilities for food processing are given in ISO/ASTM 51204[8] and ISO/ASTM 51431[10].

Dosimetry requirements and guidance for validation and operation of other irradiation facilities are given in ISO/ASTM 51608[12], ISO/ASTM 51649[13], ISO/ASTM 51702[14], and ISO 11137-3[5]. Many of the requirements and guidance in these International Standards are applicable for food irradiation facilities.

ISO/ASTM or ASTM radiation processing dosimetry standards described in ASTM E2628[18] provide requirements and guidance on dosimetry systems that might be used for dose mapping and routine monitoring of food irradiation facilities.

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