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Standard Guide for Irradiation of Finfish and Aquatic Invertebrates Used as Food to Control Pathogens and Spoilage Microorganisms[1]

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INTRODUCTION

The purpose of this guide is to present information on the use of ionizing radiation for eliminating or reducing the number of pathogenic microorganisms and parasites and for reducing the number of spoilage microorganisms on finfish and aquatic invertebrates. Information on the handling of finfish and aquatic invertebrates before receipt by the irradiation facility and after shipment from the facility is also provided.

The food commodities covered by this standard can include, but are not limited to: molluscan shellfish, crustacean shellfish, fin fish, and flat fish, including those that are saltwater, fresh water, wild caught and farm-raised.

This guide is intended to serve as a set of recommendations to be followed when using irradiation technology where approved by an appropriate regulatory control authority. It is not to be construed as setting forth rigid requirements for the use of irradiation. While the use of irradiation involves certain essential requirements to attain the objective of the treatment, some parameters can be varied in optimizing the process.

This guide is based on a guideline published by the International Consultative Group on Food Irradiation (ICGFI) at the initiation of the Joint Food and Agriculture Organization/International Atomic Energy Agency Division of Nuclear Techniques in Food and Agriculture, which serves as the Secretariat to the ICGFI.

1. Scope

1.1 This guide outlines procedures and operations for the irradiation of raw, untreated, fresh (chilled), or frozen finfish and aquatic invertebrates, while ensuring that the irradiated product is safe and wholesome.

1.1.1 Aquatic invertebrates include ~~molluses,~~mollusks, crustacea, echinoderms, etc.

1.1.1.1 ~~Molluses~~Mollusks include bivalve shellfish, such as clams, mussels, and oysters; snails; and cephalopods, such as squid and octopus.

1.1.1.2 Crustacea include shellfish such as shrimp, lobster, crabs, prawns and crayfish.

1.1.1.3 Echinoderms include sea urchins and sea cucumbers.

[1] This guide is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.05 on Food Irradiation.

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1.2 This guide covers absorbed doses used to reduce the microbial and parasite populations in aquatic invertebrates and finfish. Such doses typically are below 10 kGy (**1**).[2]

1.2.1 This guide covers gamma, electron beam, and X-radiation treatment.

1.3 The use of reduced-oxygen packaging (vacuum or modified atmosphere, and including products packed in oil) with irradiated, raw product is not covered by this guide. The anaerobic environment created by reduced-oxygen packaging provides the potential for outgrowth of, and toxin production from, *Clostridium botulinum* spores.

1.4 This guide does not cover the irradiation of smoked or dried fish to reduce microbial load or to control insect infestation.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 This document is one of a set of standards that provides recommendations for properly implementing and utilizing radiation processing. It is intended to be read in conjunction with ISO/ASTM Practice 52628.

1.7 *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~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory ~~requirements~~limitations prior to use.*

1.8 *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:*[3]

~~E170~~E3083 Terminology Relating to Radiation ~~Measurements~~ Processing: Dosimetry and ~~Dosimetry~~Applications

F1416 Guide for Selection of Time-Temperature Indicators

F1640 Guide for Selection and Use of Contact Materials for Foods to Be Irradiated

2.2 *ISO/ASTM Standards:*[3]

~~51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing~~

51261 ~~Guide for the Selection and Application of~~ Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51539 Guide for Use of Radiation-Sensitive Indicators

~~51431~~51608 Practice for Dosimetry in ~~Electron Beam and~~ an X-Ray (Bremsstrahlung) ~~Irradiation Facilities~~ Facility for ~~Food Processing~~ Radiation Processing at Energies between 50 keV and 7.5 MeV

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

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

~~51539~~52701 Guide for ~~Use of Radiation-Sensitive Indicators~~Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

2.3 *Codex Alimentarius Commission Recommended International Codes and Standards:*[4]

~~Codex Stan 1~~CAC/RCP 1-1985, Rev. 1991, and 2001 General ~~Standards~~Standard for the Labelling of Prepackaged Foods

~~Codex Stan 19~~CAC/RCP 19-1979, Rev. 2003 Recommended International Code of Practice for the Operation of Irradiation Facilities for the Treatment of ~~Food~~Foods

~~Codex Stan 106~~CAC/RCP 106-1983, Rev. 2003 ~~Codex~~ General Standard for Irradiated Foods

CAC/RCP 9 Recommended International Code of Practice for Fresh Fish

CAC/RCP 16 Recommended International Code of Practice for Frozen Fish

CAC/RCP 17 Recommended International Code of Practice for Shrimps and Prawns

CAC/RCP 18 Recommended International Code of Hygienic Practice for Molluscan Shellfish

[2] The boldface numbers in parentheses refer to the list of references at the end of this standard.

[3] 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.

[4] Available from Joint FAO/WHO Food Standards Program, Joint Office, Food and Agriculture Organization of the United Nations, Via delle Terme di Caracalla, 00100 Rome, Italy.

CAC/RCP 24 Recommended International Code of Practice for Lobsters
CAC/RCP 27 Recommended International Code of Practice for Minced Fish Prepared by Mechanical Separation
CAC/RCP 28 Recommended International Code of Practice for Crabs
CAC/RCP 37 Recommended International Code of Practice for Cephalopods
CAC/RCP 20 Code of Ethics for International Trade in Food
CAC/RCP 42 Sampling Plans for Prepackaged Foods (AQL 6.5)

2.4 *ISO Standards:*[5]
ISO 12749-4 Nuclear energy – Vocabulary – Part 4: Dosimetry for radiation processing

2.5 *International Commission on Radiation Units and Measurements (ICRU) Reports:*[6]
ICRU Report 80 Dosimetry Systems for Use in Radiation Processing
ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.6 *Joint Committee for Guides in Metrology (JCGM) Reports:*
JCGM 100:2008, GUM 1995, with minor corrections Evaluation of measurement date – Guide to the Expression of Uncertainty in Measurement[7]
JCGM 200:2012, VIM International Vocabulary of Metrology – Basic and General Concepts and Associated Terms[8]

3. Terminology

3.1 *Definitions:*

~~3.1.1 Other terms used in this guide may be defined in Terminology E170.~~

3.1.1 *absorbed dose*—~~quantity~~quotient of ~~ionizing~~dε¯ ~~radiation~~ by d*m*, where dε¯ ~~energy imparted per unit mass of specified material.~~ is the mean energy imparted by ionizing radiation to matter of mass d*m*, ~~The SI~~thus

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

~~unit for absorbed dose is the gray (Gy), where one gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1Gy = 1 J/kg).~~

3.1.1.1 *Discussion*—
~~A standard definition~~The SI unit of absorbed dose ~~appears in Terminology~~is the gray ~~E170.~~(Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J / kg).

3.1.2 *absorbed dose mapping*—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.

3.1.3 *dose distribution*—variation in absorbed dose within a process load exposed to ionizing radiation.

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

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

3.1.6 *transport system*—the conveyor or other mechanical ~~system~~means used to move the ~~product to be irradiated~~ process load through the irradiator.

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ISO/ASTM Practice 52628. Other terms that pertain to radiation measurement and dosimetry may be found in Terminology E3083 and ISO Terminology 12749-4. Where appropriate, definitions used in these standards have been derived from, and are consistent with definitions in ICRU Report 85a, and general metrological definitions given in the VIM.

[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.
[6] Available from International Commission on Radiation Units and Measurements (ICRU), 7910 Woodmont Ave., Suite 400, Bethesda, MD 20841-3095, http://www.icru.org.
[7] Document produced by Working Group 1 of the Joint Committee for Guides in Metrology (JCGM WG1). Available free of charge at the BIPM website (http://www.bipm.org).
[8] Document produced by Working Group 2 of the Joint Committee for Guides in Metrology (JCGM WG2). Available free of charge at the BIPM website (http://www.bipm.org).

4. Significance and Use

4.1 Absorbed doses of or below 1 kGy can inactivate some parasites, such as the broad fish tapeworm (*Dibothrocephalus latus*) (**2**).

4.2 Absorbed doses below 10 kGy can reduce or eliminate vegetative cells of pathogenic sporeforming and non-sporeforming microorganisms, such as ~~*Clostridia*~~*Clostridium* spp., *Vibrio* spp., *Salmonellae*,*Listeria monocytogenes*, or *Staphylococcus aureus*, that may be present in fresh or frozen product.

4.2.1 Absorbed doses below 10 kGy can reduce the numbers of some spores, but are not adequate to reduce the potential health risk from microbial spores or toxins (**3**).

4.3 Absorbed doses below 10 kGy can reduce or eliminate the vegetative cells of sporeforming and non-sporeforming microorganisms, such as *Bacillus* or *Pseudomonas* species, that cause spoilage of fresh product, thus extending refrigerated shelf life in many cases (**4**).

5. Harvest/Raw Material

5.1 Follow relevant Recommended International Codes of Practice (RCP) and Standards of Good Manufacturing Practice of the Codex Alimentarius Commission (CAC) for maintaining the initial quality of the fresh or frozen product during handling from the time of harvest through the time of sale to the consumer (**5**). See CAC/RCP 9, CAC/RCP 16, CAC/RCP 17, CAC/RCP 18, CAC/RCP 24, CAC/RCP 27, CAC/RCP 28, CAC/RCP 37, and CAC/RCP 20.

5.2 In handling, preparing, freezing, storing, and thawing finfish and aquatic invertebrates intended for irradiation, take precautions at all times to minimize microbial contamination and outgrowth. Use standards of hygiene as high as those applied in the processing or preparation of product for the frozen or fresh markets.

5.3 Deliver product to the irradiation facility without delay, such that irradiation occurs as close to the time of harvest as possible. Products approaching the end of their shelf life should not be irradiated in an attempt to extend that shelf life.

NOTE 1—While irradiation can improve finfish and aquatic invertebrates from a public health aspect by reducing the microbial and parasite populations within product, chemical reactions (for example, oxidative degradation) that cause product to spoil also need to be considered when assessing the appropriateness of radiation treatment (**6**).

6. Packaging and Product Loading Configuration

~~6.1 Packaging product prior to irradiation is one means of preventing post-irradiation contamination.~~

6.1 ~~Use packaging materials suitable to the product considering any planned processing (including irradiation) and consistent with any regulatory requirements (see Guide F1640).~~*Packaging:*

6.1.1 Guide F1640 provides guidance on packaging materials in contact with food during irradiation.

6.2 Appropriate packaging materials should be used for safeguarding the product as part of the effort to ensure product integrity (for example, see Ref (**5**)).

6.3 ~~With certain irradiation facilities, it may be necessary to limit use to particular package shapes and sizes. See ISO/ASTM Practices 51204 and 51431. Irradiation can be optimized if the product packages are geometrically well defined and uniform.~~*Product Loading Configuration:*

6.3.1 The size, shape, and loading configuration of a process load for the commodities to be irradiated should be determined primarily by considering design parameters of the irradiation facility (see ISO/ASTM 51608, 51649, and 51702). Critical irradiation parameters include the characteristics of product transport systems and of the radiation source as they relate to the dose distribution obtained within the process load. These parameters and product dose specifications should be taken into account in determining the size, shape and loading configuration of a process load (8.1).

7. Pre-Irradiation Product Handling

7.1 Inspect product as soon as it arrives at the radiation processing facility to determine that it has been properly handled prior to arrival.

7.2 *Temperature Control of Product:*

7.2.1 The temperature of fresh product, excluding unshucked, live molluscan shellfish, received in the chilled state should be maintained as close to ~~0°C (32°F)~~ 0 °C (32 °F) as possible in accordance with good manufacturing practices (GMPs). Care should be taken to prevent freezing of the product. Pre-irradiation storage at the irradiation facility should be short; less than one day is recommended.

NOTE 2—Fresh product is usually stored and transported under crushed, melting ice. When refrigeration is used, the risk of freezing exists.

7.2.2 The temperature of unshucked, live molluscan shellfish received in the chilled state should be maintained between ~~4°C (39°F) and 7°C (45°F)~~ 4 °C (39 °F) and 7 °C (45 °F) in accordance with GMPs. Pre-irradiation storage at the irradiation facility should be short; less than one day is recommended.

NOTE 3—To maintain unshucked molluscan shellfish in the live state, the storage temperature should be above ~~4°C (39°F).~~4 °C (39 °F).

7.2.3 The surface temperature of product received in the frozen state should be maintained below ~~−18°C (0°F).~~ −18 °C (0 °F).

NOTE 4—Freezing does not provide an unlimited shelf life without loss of quality, and the pre-irradiation storage period should therefore be minimized. The effect of frozen storage on product quality will be a function of time, temperature, and degree of temperature fluctuation.

7.2.4 Handling and storage procedures that differ from those described in Sections 5 and 6, especially holding under refrigeration for an unduly long time, do not constitute GMP. Such treatment may result in excessive bacterial growth and undesirable changes in the products.

7.3 Inspect all shipping documents arriving with the shipment to verify that they are complete and accurate.

7.3.1 The documents should include a lot number or other means of traceability (see 12.1).

7.4 *Product Separation*—~~Use~~ It may not be possible to distinguish irradiated from non-irradiated product by inspection. It is therefore important that appropriate means, such as physical barriers, ~~to keep non-irradiated and irradiated product separated at all times while at the irradiation facility. This is necessary because it may not be possible to distinguish non-irradiated from irradiated product by inspection.~~or clearly defined areas, be used to maintain non-irradiated product separate from irradiated product.

NOTE 5—Radiation-sensitive indicators (RSIs), such as labels, papers, or inks that undergo a color change when exposed to radiation in the pertinent dose range are commercially available. These indicators may be useful within the irradiation facility as a visual check for determining whether or not a product has been exposed to the radiation source. They are not dosimeters intended for measuring absorbed dose and must not be used as a substitute for proper dosimetry. Information about dosimetry systems and the proper use of RSIs is provided in Guides ~~51261~~51261 and ~~51539~~51539~~,~~, 52628 and 52701 respectively.

7.5 Plan preparatory operations for irradiation, such as, but not limited to, dosimeter placement and reconfiguration of product in the product unit, to permit expeditious handling of consecutive batches. These preparatory steps, in addition to the placement of the product on the transport system and the time required for the irradiation treatment contribute to the cumulative time and temperature exposure that will influence the extent of deterioration by chemical or biological mechanisms or the development of microorganisms of public health ~~significance (see Practices 51204 and 51431, and Guide 51261).~~significance.

7.5.1 The size, shape, and product-loading configuration of a product unit used to hold product for irradiation are determined largely by certain design parameters of the irradiation facility. Critical parameters include the characteristics of product transport systems and of the radiation source as they relate to the dose distribution obtained within the product unit. Pre-determined minimum and maximum dose limits may also influence the choice of size, shape, and product-loading configuration of the product unit.

8. Irradiation

8.1 *Scheduled Process*—Irradiation of food should conform to a scheduled process. A scheduled process for food irradiation is a written procedure that is used to ensure that the absorbed-dose range and irradiation conditions selected by the radiation processor are adequate under commercial processing conditions to achieve the intended effect on a specific product in a specific facility. The scheduled process should be established by qualified persons having expert knowledge of the irradiation requirements specific for the food and the processor's irradiation facility (**7**).

8.2 *Standard Operating Procedures (SOPs)*—Standard operating procedures for food irradiation are documented procedures that are used to ensure that the established dose range and irradiation conditions selected by the radiation processor are achievable and adequate under commercial processing conditions to achieve the intended effect on a specific product in a specific facility. These procedures should be established and validated by qualified persons having knowledge in irradiation requirements specific for the food and the irradiation facility (see CAC/RCP 19).

8.2.1 Installation qualification, operational qualification, performance qualification and process control should be performed following the requirements of ISO/ASTM Practice 51702, ISO/ASTM Practice 51608, or ISO/ASTM Practice 51649.

8.3 *Radiation Sources*—The sources of ionizing radiation that may be employed in irradiating food are limited to the following (see Codex Stan 106):

8.3.1 *Isotopic Sources*—Gamma rays from the radionuclides ^{60}Co (1.17 and 1.33 MeV) or ^{137}Cs (0.66 MeV), and

8.3.2 *Machine Sources*—X-rays and accelerated electrons.

NOTE 6—The Codex Alimentarius Commission, as well as regulations in some countries, currently limit the maximum electron energy and nominal X-ray energy for the purpose of food irradiation (Codex Stan 106).

8.4 *Absorbed Dose*—Food irradiation specifications may include minimum and maximum absorbed dose limits. A minimum absorbed dose may be specified to ensure that the intended effect is achieved, and a maximum absorbed dose may be based on government regulations resulting from a safety assessment or be stipulated to prevent product degradation. For a given application, one or both of these limits may be prescribed by regulation. It is therefore necessary, prior to the irradiation of product, to establish an irradiation protocol that will ensure that the absorbed dose requirements can be satisfied. This is accomplished through absorbed-dose mapping to determine the magnitudes and locations of the minimum and maximum absorbed doses in the product units at the time of actual processing. It is necessary to identify and record the absorbed-dose extremes for each production run. For more information on these dosimetric procedures, see Practices 51702~~51204~~, 51608 and ~~51431~~51649 and ~~Guide~~Guides 52628~~51261.~~ and 52701.

NOTE 7—In general, irradiation of the same product more than once is not recommended. See Codex Stan 106.

8.4.1 *Dosimetry*—Dosimetry is a major component of a total quality assurance program for adherence to good manufacturing practices used in radiation processing of food. CX STAN 106 and CAC/RCP 19 strongly emphasize the role of dosimetry for ensuring that irradiation is properly performed, since dosimetry is part of a verification process for establishing that the irradiation process is under control.

8.4.2 *Dosimetry System*—Dosimetry used in the development, validation and routine control of the irradiation process shall have measurement traceability to national or international standards and shall have a known level of uncertainty. The selected dosimetry system should be appropriate for the radiation source being used, the range of absorbed doses required, and the environmental conditions (for example, product temperature, irradiation temperature) expected during irradiation (see ISO/ASTM 51261, 52628 and 52701). (**8**)

8.4.3 *Absorbed-dose Mapping*—Prior to performing routine irradiation, it is necessary to characterize the dose distribution in the volume of product being irradiated through absorbed dose mapping. Dosimeters placed throughout the product provide dose measurements to identify the magnitude and location of minimum and maximum dose. The absorbed dose map depends on the product, how the product is packaged and oriented in the package, the packaging material, and presentation to the irradiation source. Guidance on dose mapping is given in ISO/ASTM 52303.

~~NOTE 7—In general, irradiation of the same product more than once is not recommended. See Codex Stan 106.~~

8.5 *Routine Production Dosimetry*—The irradiation facility is responsible for delivering the absorbed doses within the specified dose range. Dosimetry should be performed following the requirements of ISO/ASTM Practice 51702 for Gamma Facility for Radiation Processing, ISO/ASTM Practice 51608 for X-Ray (Bremsstrahlung) Facility for Radiation Processing at Energies between 50 keV and 7.5 MeV, or ISO/ASTM Practice 51649 for Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV. Once the radiation facility has demonstrated the ability to deliver the absorbed dose, it is necessary to monitor, and record absorbed dose values during routine processing. (See 12.1.3.)

8.5.1 Routine dosimetry is part of a verification process for establishing that the irradiation process is under control.

8.5.2 Select and calibrate a dosimetry system appropriate to the radiation source being used, the environmental conditions, and the range of absorbed doses required (see ISO/ASTM 51261 and Refs **(9)** and **(10)**).

8.5.2.1 Verify that the product routinely receives the required absorbed dose by using proper dosimetry procedures, with appropriate statistical controls and documentation.

8.5.2.2 Place dosimeters in or on the process load at regions of minimum and maximum absorbed dose. These locations are identified in the product absorbed-dose mapping exercise. If the minimum and maximum dose locations are not accessible, place dosimeters at routine monitoring positions where the dose values have known and quantifiable relationships to the minimum and maximum doses. These routine monitoring positions should be identified during absorbed-dose mapping exercise.

8.6 *Product Temperature*—During irradiation, maintain the temperature of unshucked, live molluscan shellfish between ~~4°C (39°F) and 7°C (45°F).~~ 4 °C (39 °F) and 7 °C (45 °F). Maintain the temperature of all other fresh product below ~~4°C (39°F).~~ 4 °C (39 °F). Maintain frozen product below ~~−18°C (0°F)~~ −18 °C (0 °F) during processing.

NOTE 8—Absorbed doses up to 2 kGy are not lethal to unshucked molluscan shellfish. Therefore, temperatures during irradiation should be kept between ~~4°C and 7°C~~ 4 °C and 7 °C to maintain their viability (**811**, **912**). The upper limit of 4°C for fresh product other than unshucked, live molluscan shellfish was developed with regard to *C. botulinum* Type E (*C. botulinum* may grow below ~~4°C~~ 4 °C, but not produce toxin over the shelf life of the product. Therefore, the *C. botulinum* hazard is not likely to occur for products covered by this standard (see 1.3). Usually, the heat capacity of chilled or frozen product is large enough to maintain the product temperature, even at the surface, during the relatively short time needed for irradiation.

8.6.1 In cases where product is irradiated in melting ice, provisions should be made to collect and discard the drip from the melting ice for sanitation and prevention of facility contamination.

9. Post-Irradiation Handling and Storage

9.1 Handle and store irradiated product in the same manner as non-irradiated product, that is, in accordance with GMPs, to avoid recontamination. For fresh product, excluding unshucked, live molluscan shellfish received in the chilled state, maintain the post-irradiation temperature as close to ~~0°C (32°F)~~ 0 °C (32 °F) as possible. For unshucked, live molluscan shellfish irradiated in the chilled state, maintain the post-irradiation temperature between 4°C (39°F) and ~~7°C (45°F).~~ 7 °C (45 °F). For all frozen product, maintain the temperature below ~~−18°C (0°F).~~ −18 °C (0 °F).

NOTE 9—Some chill rooms may not be designed to cool product but only to maintain the temperature after it has been cooled by ice or other means.

9.2 Use appropriate means, such as physical barriers, to keep irradiated product separated from non-irradiated product at all times while at the irradiation facility. This is necessary because it may not be possible to distinguish irradiated product from non-irradiated product by inspection. Radiation Sensitive indicators may be useful (see Note 5) as an additional means for indicating that product has passed through the irradiation zone.

10. Criteria for Assessing Irradiation Efficacy

10.1 An irradiation protocol should be designed to accomplish specific goals, such as reduction of pathogens or extension of shelf life of product. Proper dosimetric procedures should be followed to ensure that the absorbed dose necessary to accomplish those goals has been delivered to the product. The following criteria may be used to aid in the design of the irradiation protocol:

10.1.1 *Irradiation for Control of Pathogenic Bacteria*—The numbers of pathogenic bacteria that can result in an infectious product vary with the specific bacterial strain and the susceptibility of the consumers involved. The adoption of criteria analogous to those