Designation: F1356 – 16

Standard Guide for Irradiation of Fresh, Frozen or Processed Meat and Poultry to Control Pathogens and Other Microorganisms[1]

This standard is issued under the fixed designation F1356; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

The purpose of this guide is to present information on the use of ionizing radiation in treating fresh, frozen, or processed meat and poultry products to eliminate or reduce the numbers of vegetative, pathogenic microorganisms and parasites, and to extend the refrigerated shelf-life of those products by reducing the numbers of spoilage microorganisms.

This guide is intended to serve as a set of recommendations to be followed when using irradiation technology where approved by an appropriate regulatory 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 has been prepared from a Code of Good Irradiation Practice published by the International Consultative Group on Food Irradiation (ICGFI) developed under the auspices of the Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the International Atomic Energy Agency (IAEA) (**1**).[2]

1. Scope

1.1 This guide outlines procedures for the irradiation of fresh, frozen, or processed meat and poultry.

NOTE 1—The Codex Alimentarius Commission defines meat as "the edible part of any mammal" and poultry as "any domesticated bird, including chicken, turkeys, ducks, geese, guinea-fowls, or pigeons" (CAC/MISC 5).

NOTE 2—Current U.S. regulations limit the definition of meat and poultry as listed in 9 CFR Section 301.2 and 381.1, respectively. (**2, 3**).

1.2 This guide covers the use of ionizing radiation to eliminate or reduce the numbers of vegetative, pathogenic microorganisms and parasites, and to extend the refrigerated shelf-life of those products by reducing the numbers of spoilage microorganisms in fresh, frozen, or processed meat and poultry. The absorbed dose for this application is typically less than 10 kGy.

1.3 This guide addresses irradiation of pre-packaged product for retail sale or for use as an ingredient in other products. It also addresses the in-line irradiation of unpackaged product. Other specific ISO and ASTM standards exist for the irradiation of food. In those areas covered by ISO 14470, that standard takes precedence.

1.4 *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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E170 Terminology Relating to Radiation Measurements and Dosimetry

F1416 Guide for Selection of Time-Temperature Indicators

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

2.2 *ISO/ASTM Standards:*[3]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51539 Guide for Use of Radiation-Sensitive Indicators

51608 Practice for Dosimetry in an X-Ray (Bremsstrahlung)

[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.

Current edition approved Feb. 1, 2016. Published March 2016. Originally approved in 1991. Last previous edition approved in 2008 as F1356 – 08. DOI: 10.1520/F1356-16.

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

[3] For referenced ASTM and ISO/ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

Facility for 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
51818 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV
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 *Codex Alimentarius Commission Recommended International Codes and Standards:*[4]
CAC/RCP 1-1969, Rev. 4-2003, Recommended International Code of Practice—General Principles of Food Hygiene including Annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application
CAC/RCP 19-1979, Rev. 2003, Recommended International Code of Practice for the Radiation Processing of Food
CX STAN 1-1985, Rev. 2010, General Standard for the Labeling of Prepackaged Foods
CX STAN 106, Rev. 2003, General Standard for Irradiated Food
CAC/MISC 5-1993, Amd. 2003, Glossary of Terms and Definitions (Veterinary Drug Residues in Food)
CAC/GL21-1997, Rev. 2013, Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Food

2.4 *ISO Standard*[5]
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

3. Terminology

3.1 *Definitions:*

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

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

$$D = d\bar{\varepsilon}/dm \quad (1)$$

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

3.1.3 *D_{10} value*—absorbed dose required to reduce the microbial population in a given food by 90 %.

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

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

3.1.6 *transport system*—conveyor or other mechanical system used to move the process load through the irradiator.

4. Significance and Use

4.1 The principal purpose of irradiation is to help ensure the safety of these foods for human consumption. Irradiation significantly reduces the numbers of pathogenic bacteria such as *Campylobacter*, *Shiga toxin-Producing E coli*, *Listeria monocytogenes*, *Salmonella*, *Staphylococcus aureus*, and *Yersinia enterocolitica*.

NOTE 3—Ionizing radiation doses below 10 kGy will reduce but may not eliminate spores of pathogenic bacteria uncluding those of *Clostridium botulinum*, *Clostridium perfringens*, and *Bacillus cereus*.

4.2 The process also inactivates parasites such as *Trichinella spiralis* and *Toxoplasma gondii*.

4.3 The process may extend the shelf life of fresh meat and poultry by reducing the numbers of viable, spoilage bacteria, such as *Pseudomonas* species and lactic acid bacilli.

4.4 Radiation processing of fresh, frozen, or processed meat and poultry is a critical control point (CCP) of a Hazard Analysis of Critical Control Points (HACCP) program. It serves as an important measure to control any residual risk from pathogenic microorganisms before the product reaches the consumer (**4**).

4.5 The "Recommended International Code of Practice for Radiation Processing of Food" (CAC/RCP 19-1979) of the Codex Alimentarius identifies the essential practices to be implemented to achieve effective radiation processing of food, in general, in a manner that maintains quality and yields food products that are safe and suitable for consumption.

5. Criteria for Assessing Process Control and Irradiation Efficacy

5.1 *Process Control System*—The criterion should be that hazard analysis and critical control point (HACCP) system or another similar process control system is applied to the entire processing and distribution chain. With this system, any point in the chain where a hazardous or critical situation could result is monitored and controlled to prevent unsafe and unwholesome product from reaching the consumer. See CAC/RCP 1 and (**4**, **5**). Failure to meet these criteria should be investigated, to assess the efficacy of standard operating procedures (see 8.1) and the re-establishment, if necessary, of Good Manufacturing Practice (GMPs).

5.1.1 Implementation of a process control system (see 4.4) to assess radiation-processing efficacy should include bacteriological examination of the product before and after irradiation, use of time/temperature indicators throughout the processing chain (see Guide F1416), and testing of package integrity. Irradiation efficacy has to be validated to ensure that the minimum absorbed dose delivered (see 8.3–8.4) to the product

[4] Available from the Joint FAO/WHO Food Standards Programme, Joint Office, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

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

is able to achieve the minimum reduction in target microbial organisms that is expected. The target organism(s) have to be identified prior to this validation. Bacteriological testing after specific irradiation doses should yield a predicted decline in viable counts of the target pathogen(s). Temperature monitoring should provide an alert of any product abuse that could result in increases in bacterial counts after irradiation.

5.2 *Criteria for Irradiation Treatment:*

5.2.1 *Irradiation for Control of Pathogenic Bacteria*—The criterion should be that the irradiation treatment is able to reduce the number of pathogenic bacteria in the meat or poultry, such that they are no longer able to cause illness. Determining whether a specified irradiation treatment will reduce the likelihood of illness can only be based on a formal quantitative microbial risk assessment (QMRA) approach (**6, 7**). The numbers of pathogenic bacteria that can result in an infectious product vary with the specific bacterium.

NOTE 4—Susceptibility of a person to pathogenic bacteria varies and is based on the health of the individual and the virulence of the particular strain of the pathogen (**8, 9**).

5.2.2 *Irradiation for Inactivation of Parasites*—The criterion should be that the parasites in uncooked, irradiated product are noninfectious or noninvasive, as appropriate.

5.2.3 *Irradiation for Shelf-Life Extension*—The criterion should be the bacterial plate count using appropriate time, temperature, and media parameters. Reduction in bacterial counts as final criteria cannot be specified unless local regulations, customer specifications, or both, are known. Therefore, the final product specification regarding bacterial plate count should be established by the food producer or food processor.

6. Pre-Irradiation Product Handling

6.1 Product handling should be under conditions that protect the product against physical, chemical, or biological hazards. Microbial contamination and growth should be minimized by following relevant standards of GMPs; see for example U.S. Food and Drug Administration (FDA) GMPs (**10**), U.S. Food Safety and Inspection Service (FSIS) Standard Sanitary Operating Procedures (SSOPs) (**11**), CAC Recommended International Codes of Practice, (CAC/RCP 1 (see 2.3) and HACCP) (**4, 5, 12**).

6.2 *Unpackaged Product*—In facilities handling unpackaged product, the irradiation environment and equipment should be designed and constructed to be cleanable and durable to maintain a sanitary condition and, thereby, not increase the risk of contamination.

NOTE 5—An operating environment with high moisture or airflow may contribute to the risk of bacterial contamination. Moisture provides a growth medium for bacteria and airflow provides a means of transport for bacteria. Food contact surfaces may contribute chemical or physical contaminants to products unless such surfaces are fabricated from appropriate materials and properly maintained and cleaned. Also, employee hygiene and pest control should be closely monitored.

6.3 *Pre-Packaged Product*—For pre-packaged product, the package itself provides a barrier that helps to reduce the risk of recontamination. Thus, many of the requirements for the irradiation environment and equipment necessary for handling unpackaged product may not be applicable for facilities handling only pre-packaged product. Information on applicable requirements should be obtained from the appropriate regulatory authorities before starting operations.

6.4 *Pre-Irradiation Inspection*—Packages and containers of fresh, frozen, or processed meat and poultry should be inspected upon receipt at the irradiation facility to ensure that the product is suitable for irradiation. Written acceptance criteria for product temperature, package integrity and inspection frequency, as applicable, should be established by the product owner and agreed to by management of the irradiation facility prior to accepting product from the owner. Also, criteria for handling of product unsuitable for irradiation should be established.

6.4.1 *Product Temperature*—Upon receipt of product, its temperature should be measured using a calibrated sanitized temperature-sensing device, at a predetermined location and frequency as specified by HACCP and GMPs. Temperature should be between –2 and +4°C for refrigerated fresh or processed meat and poultry or –18°C or lower for frozen meat and poultry. For unpackaged product, insert the device directly into the product and sanitize the device between each measurement. For prepackaged product, use a device that can be placed between individual packages without puncturing them.

6.4.2 *Package Integrity*—A visual inspection of the product packaging should be performed to ensure there is no evidence of compromised or damaged product. Also, a sensory inspection should be performed. No leakage of fluids or odor indicative of product spoilage should be evident upon inspection.

6.4.3 *Product Inventory*—The number of containers should be counted and the description/identification of the product to be irradiated should be verified and compared with the documentation from the product owner. A comparison of this pre-irradiation count with a count performed after irradiation provides a check that all products received have been irradiated.

6.4.4 *Product Identification*—A unique identification number for tracking the product throughout the irradiation process should be issued and documented for the incoming product.

6.5 *Pre-Irradiation Storage:*

6.5.1 *Refrigerated Fresh or Processed Meats and Poultry*—The principal requirement for pre-irradiation storage is to maintain product temperature between –2 and +4°C without freezing. Whenever possible, the pre-irradiation storage at the irradiation facility should be minimized to one day or less.

NOTE 6—U.S.A. poultry regulations presently require that the temperature of fresh poultry be maintained at or below 4.4°C (**12**).

NOTE 7—Holding product under refrigeration for an unduly long time would violate principles of GMPs because such treatment may result in excessive growth of psychrotrophic bacteria and undesirable changes in products.

6.5.2 *Frozen Meats and Poultry*—The product temperature should be maintained at or below –18°C at all times.

6.6 *Product Segregation*—Distinguishing irradiated from un-irradiated product by visual inspection might not be possible. Therefore, it is important that appropriate means integral

to the facility design, such as physical barriers or clearly defined staging areas, be used to maintain un-irradiated product separate from irradiated product.

NOTE 8—Radiation-sensitive indicators undergo a color change when exposed to radiation in the pertinent dose range. These indicators may be useful within the irradiation facility to provide a visual check for determining whether or not 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 radiation-sensitive indicators is provided in ISO/ASTM Practice 52628 and ISO/ASTM Guide 51539, respectively.

7. Packaging and Product Loading Configuration

7.1 *Packaging Materials:*

7.1.1 Use packaging materials suitable to the product, that take into account planned processing (including irradiation) and is consistent with regulatory requirements (see Guide F1640).

7.1.2 Packaging materials should provide appropriate gas and moisture permeability to maintain product quality.

NOTE 9—There are mechanisms other than bacterial action that cause meat spoilage. These are largely chemical in nature and generally involve oxidation of the product, resulting in discoloration and rancidity. Other measures in addition to irradiation may be necessary to obtain a satisfactory product. Where applicable, a package providing a reduced oxygen environment (for example, vacuum packaging) minimizes such effects.

NOTE 10—Fresh meats, especially the more highly pigmented ones such as beef, ordinarily require the presence of oxygen in order to maintain their normal red color. The use of vacuum packaging and oxygen-impermeable films causes meat to darken in the package, although the normal red color will return when the package is opened. For the less pigmented meat and for poultry, the color change resulting from vacuum packaging is less significant.

7.2 *Product Loading Configuration:*

7.2.1 The size, shape, density and loading configuration of a process load to be irradiated should be determined primarily by considering design parameters of the irradiation facility. Critical design parameters include the characteristics of product transport systems and of the radiation source as they relate to the dose distribution determined within the process load.

7.2.2 The dose distribution within the process load can often be optimized by using product packages that are geometrically well defined and uniformly loaded. 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 (see ISO/ASTM 51608, 51649, 51702, and 51818).

7.2.3 Prescribed product dose specifications should be taken into account when determining the appropriate product-loading configuration (see 8.4).

8. Irradiation

8.1 *Standard Operating Procedures (SOPs)*—A standard operating procedure for food irradiation is a documented procedure that is used to ensure that the technologically established dose range and irradiation conditions selected by the radiation processor are achievable in a specific facility. The procedures should be established by qualified persons having knowledge in irradiation requirements specific to the food and the irradiation facility (**13**). The procedures should meet the requirements of CX STAN 106 and should follow the recommendations of CAC/RCP 19, including installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ).

8.2 *Radiation Sources*—The sources of ionizing radiation that should be employed for irradiating fresh, frozen, or processed meat and poultry products are limited to the following (see CX STAN 106):

8.2.1 *Isotopic Sources*—Gamma rays from the radionuclides ^{60}Co (1.17 and 1.33 MeV) and ^{137}Cs (0.66 MeV) (see ISO/ASTM Practice 51702;

8.2.2 *Machine Sources*—X-rays and accelerated electrons (see ISO/ASTM Practice 51608 and ISO/ASTM Practice 51649).

NOTE 11—The Codex Alimentarius Commission as well as regulations in some countries currently limit the maximum electron energy and X-ray energy for the purpose of food irradiation (CX STAN 106).

8.3 *Absorbed Dose:*

8.3.1 *Absorbed Doses Required to Accomplish Specific Effects*—The food producer or food processor should provide required minimum and maximum absorbed dose limits (**14**): the lowest dose necessary to ensure the intended effect (for example, microbial load reduction, pathogen inactivation), and the highest dose that does not negatively affect the product quality through the formation of off-flavors, aromas, and color changes (**14-16**). One or both of these limits may be prescribed by government authorities for a given application. The sensitivity of meat and poultry to irradiation varies with the type of product, product formulation for processed meats, the packaging atmosphere, the product temperature during irradiation, and other factors. A higher minimum dose may be required for frozen product than for product irradiated in a refrigerated state to achieve the same intended objective because bacterial resistance to radiation damage is higher at sub-freezing temperatures (**17, 18**).

8.3.2 *Absorbed Dose for the Control of Pathogenic Bacteria*—Pathogenic bacteria that may be present in or on fresh, frozen, or processed meat and poultry products include *Salmonella* species, *Campylobacter jejuni*, *Shiga toxin-Producing E coli*, *Staphylococcus aureus*, *Listeria monocytogenes*, and *Yersinia enterocolitica*. The absorbed dose required to reduce the numbers of these bacteria to levels commensurate with product that is safe for consumption depends on a number of criteria. The required absorbed dose range should be established on the basis of the microbial load in the un-irradiated product, the radiation sensitivity of the bacteria present, the temperature of the product during irradiation, the controlled atmosphere surrounding the packaged product during irradiation, and the regulatory or customer requirement for acceptable residual numbers of bacteria. Appendix X1 provides some information, taken from the scientific literature, about the radiation sensitivity (D_{10} values) of the principal pathogenic bacteria found in meat and poultry products.

8.3.3 *Absorbed Dose for Inactivation of Parasites*—Most parasites will be rendered noninfectious by absorbed doses of less than 1 kGy. The minimum effective absorbed dose will depend on the specific parasite to be inactivated (**16, 18-25**).

8.3.4 *Absorbed Dose for Shelf-Life Extension*—The absorbed dose that produces an extension of shelf life of fresh, frozen, or processed meat and poultry products depends on the initial level of the bacterial load and the radiation sensitivity of the bacteria present.

8.4 *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 will be properly performed, since dosimetry is part of a verification process for establishing that the irradiation process is under control.

8.4.1 *Dosimetry System*—Select and calibrate, traceable to national or international standards, a dosimetry system appropriate for the radiation source being used, the range of absorbed doses required, and the environmental conditions (for example, product temperature, irradiation cell temperature) expected during irradiation (see ISO/ASTM 51261, 52628 and 52701(**15**).

8.4.2 *Dose Mapping*—Prior to performing routine irradiation of meat and poultry, it is necessary to characterize the dose distribution in the volume of product being irradiated. The dose mapping of a specific process load identifies the dose delivered in specifically identified area throughout the product. Dosimeters placed throughout the product provide dose measurements to identify the magnitude and location of high and low dose zones. The dose map is unique for each product based on what the product is, 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.

8.4.3 *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 Practices 51702, 51608, 51649, or 51818.

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

8.4.3.2 Place dosimeters in or on the process load at regions of minimum and maximum absorbed dose (D_{min} and D_{max}). These locations are identified in the product absorbed-dose mapping exercise. If the D_{min} and D_{max} locations are not accessible, place dosimeters at routine monitoring positions where the dose values have known and quantifiable relationships to D_{min} and D_{max}.

8.5 *Product Temperature:*

8.5.1 Measure and document the temperature of the product as it enters and exits the irradiator to ensure that requirements of the facility SOPs have been met.

8.5.2 If the temperature of the irradiation area and the time required to achieve the desired absorbed dose result in a rise in product temperature outside the specified limits, conditions of the process are not being met. Appropriate changes to the process should be made that could include insulation of the product load or refrigeration of the irradiation area. If the product is insulated during irradiation, the addition of the insulating material will require the process load to be re-characterized for absorbed-dose distribution.

NOTE 12—Temperature control of the product is critical as a food safety intervention during irradiation because bacteria multiply more rapidly as temperature rises. For example, the number of *Listeria* in a meat or poultry product can double much faster at ambient temperatures, than at refrigerated temperatures (**26**).

8.6 *Incremental Irradiation*—Incremental irradiation is the application where the specified dose is delivered in multiple irradiation exposures, to minimize the temperature rise of the product. Keep product that has received a portion of the total specified dose separate from un-irradiated product and product for which the dose requirements have been met. In addition, the product should be maintained in the required temperature range and the time interval between irradiation exposures should be kept to a minimum.

9. Post-Irradiation Handling and Storage

9.1 *Post-Irradiation Inspection*—Inspect packages or containers of meat and poultry after irradiation to ensure that the product meets requirements of established procedures (see 8.1) in accordance with the provisions of the Recommended International Code of Practice – General Principles of Food Hygiene.

9.2 *Post-Irradiation Labeling*—Some consumers and food processors may wish to distinguish between irradiated and un-irradiated products, thus many governments have adopted labeling requirements (see 5.2 of CX STAN 1). Labeling will identify the product as irradiated and can inform the consumer of the purpose and benefits of the treatment as well as handling or storage requirements (see 9.3 and 9.4).

NOTE 13—Labeling requirements differ among different national authorities. Food producers and food processors should always contact such authorities before designing labeling materials. An increasing number of countries are adopting the internationally recognized "Radura" symbol as a means of labeling (see Fig. 1). In some countries, for example the U.S.A. (**27**), the symbol must be accompanied by a statement, such as "Treated with Radiation" or "Treated by Irradiation."

9.3 *Post-Irradiation Handling*—Handling of fresh, frozen or processed meat and poultry product in an irradiation facility should be in accordance with relevant and current GMPs. Measures should be in place for ensuring segregation of irradiated and un-irradiated product. Distinguishing irradiated from un-irradiated product by visual inspection might not be possible. Therefore, the use of appropriate means, such as radiation indicators, physical barriers, or clearly defined staging areas to maintain un-irradiated product separate from irradiated product is important.

FIG. 1 Radura Logo

9.3.1 *Product Temperature*—After irradiation, bring fresh product to a temperature between –2 and +4°C within the time necessary to prevent growth of any surviving bacteria. Bring frozen product to a temperature at or below –18°C as soon as possible after irradiation.

9.3.2 *Package and Product Integrity*—Inspect the packages to ensure that there is no leakage of fluids or odor indicative of product spoilage. If vacuum packaging or oxygen-free modified atmosphere packaging is used, particular care must be taken to ensure that the storage temperature is controlled at or below 4°C in order to prevent abuse of the product and subsequent outgrowth of *C. botulinum*.

9.3.3 *Product Inventory*—Count the number of containers irradiated. A comparison of this information with a count performed before irradiation provides a check that all product received has been irradiated or otherwise accounted for and so documented.

9.4 *Post-Irradiation Storage*—Store irradiated products in the same manner as un-irradiated products. For fresh product, the temperature should be maintained between –2 and +4°C at all times during storage. For frozen product, the temperature should be maintained at or below –18°C at all times during storage.

10. Documentation

10.1 Ensure that each lot of product to be processed carries an identification number or other code that will distinguish it from other lots of product in the facility. Use this identification on all lot documents.

10.2 Establish a record of the irradiation process.

10.2.1 Record and document the number of containers in the lot and the physical condition, the date it arrives at the facility, the temperature and condition of the lot upon receipt, the date it is irradiated, the starting and ending times of the irradiation, the temperature rise during irradiation, the temperature and condition of the lot after irradiation, the date the lot leaves the facility, the name of the operator, and any special conditions that could affect the irradiation process or the irradiated product.

10.2.2 Record and document all dosimetry data associated with product absorbed-dose mapping and routine processing (see ISO/ASTM Practices 51608, 51649, 51702, and 51818) **(12, 28)**.

10.2.3 Record and document any deviation from the SOP in order to assess the validity of the process.

10.3 Audit all documentation prior to product release to ensure that records are accurate and complete. The person making the audit should sign the documentation. Collect/place reports about deficiencies in a separate file available for examination by a regulatory authority.

10.4 Retain all records for each lot irradiated at the facility for the period of time specified by relevant authorities and have them available for inspection as needed **(18)**.

11. Keywords

11.1 bacteria; cattle; chicken; duck; electron beam; equine; food; gamma radiation; goat; goose; guinea; HACCP; horse; irradiation; labeling; meat; microorganisms; mule; packaging; parasites; pathogens; pigeons; poultry; processed; processing; sheep; swine; turkey; X-radiation; X-ray

APPENDIXES

(Nonmandatory Information)

X1. RADIATION SENSITIVITY OF BACTERIA FOUND IN MEAT AND POULTRY PRODUCTS

X1.1 Table X1.1 provides some information, taken from the scientific literature, about the radiation sensitivity (D_{10} values) of the principal pathogenic bacteria found in meat and poultry products.

TABLE X1.1 D_{10} Values (kGy) for Foodborne Pathogens in Meat and Poultry at Irradiation Temperatures of 5 and –20°C

Pathogen	D_{10} Value (kGy) @ 5°C	D_{10} Value (kGy) @ –20°C	Reference
Campylobacter jejuni	0.18 ± 0.01	0.24 ± 0.02	A
Shiga Toxin-Producing E coli	0.31 ± 0.03	0.57	B,C,D
	0.24 ± 0.01	0.31 ± 0.02	A
	0.54 ± 0.01		E
Listeria monocytogenes	0.45 ± 0.03	1.21 ± 0.06	C,D,E
	0.59 ± 0.06	0.61 ± 0.04	F
	0.61 ± 0.06		G
Salmonella species	0.41 ± 0.00	0.63 ± 0.00	H
	0.70 ± 0.04	0.92	D,I
	0.62 ± 0.09	0.80 ± 0.05	A
	0.64 ± 0.02		E
Staphylococcus aureus	0.46 ± 0.02	0.74	D,J,K
	0.45 ± 0.04	0.45 ± 0.04	H
	0.66 ± 0.01		E
Yersinia enterocolitica	0.19 ± 0.02	0.40 ± 0.01	L
	0.25 ± 0.01	0.25 ± 0.01	M

[A] Clavero, M. R. S., Monk, J. D., Beuchat, L. R., Doyle, M. P., and Brackett, R. E., "Inactivation of *Escherichia coli* O157:H7, *Salmonellae*, and *Campylobacter jejuni* in Raw Ground Beef by Gamma Irradiation," *Appl. Environ. Microbiol.*, Vol 60, 1994, pp. 2069–2075.
[B] Sommers, C. H., Rajkowski, K. T., Scullen, O. J., Cassidy, J., Fratamico, P., Sheen, S., "Inactivation of Shiga Toxin-Producing Escherichia coli in lean ground beef by gamma irradiation," *Int. J. Food Microbiol.*, 49:2015, 231-234.
[C] Thayer, D. W., and Boyd, G., "Elimination of *Escherichia coli* O157:H7 in Meats by Gamma Irradiation," *Appl. Environ. Microbiol.*, Vol 59, 1993, pp. 1030–1034.
[D] Thayer, D. W., Boyd, G., Fox Jr., J. B., Lakritz, L., and Hampson, J. W., "Variations in Radiation Sensitivity of Foodborne Pathogens Associated with the Suspending Meat," *J. Food Sci.*, Vol 60, 1995, pp. 63–67.
[E] Jo, C., Lee, N. Y., Kang, H. J., Shing, D. H., and Byun, M. W., "Inactivation of foodborne pathogens in marinated beef rib by ionizing radiation," *Food Microbiol.*, 21: 2004, 543-548.
[F] Thayer, D. W. and Boyd, G., "Radiation Sensitivity of *Listeria monocytogenes* on Beef as Affected by Temperature," *J. Food Sci.*, Vol 60, 1995, pp. 237–240.
[G] Sommers, C. H., and Thayer, D. W., "Survival of surface-inoculated Listeria monocytogenes on commercially available frankfurters following gamma irradiation," *J. Food Safetry*, 2000. pp. 127-137.
[H] Monk, J. D., Clavero, M. R. S., Beuchat, L. R., Doyle, M. P., and Brackett, R. E., "Irradiation Inactivation of *Listeria monocytogenes* and *Staphylococcus aureus* in Low- and High-Fat, Frozen and Refrigerated Ground Beef," *J. Food Prot.*, Vol 57, 1994, pp. 969–974.
[I] Previte, J. J., Chang, Y., and El Bisi, H. M., "Effects of Radiation Pasteurization on *Salmonella*. I. Parameters Affecting Survival and Recovery from Chicken," *Can. J. Microbiol.*, Vol 16, 1970, pp. 465–471.
[J] Thayer, D. W. and Boyd, G., "Survival of *Salmonella typhimurium* ATCC 14028 on the Surface of Chicken Legs or in Mechanically Deboned Chicken Meat Gamma Irradiated in Air or Vacuum at Temperatures of –20 to +20°C," *Poultry Science*, Vol 70, 1991, pp. 1026–1033.
[K] Thayer, D. W. and Boyd, G., "Gamma Ray Processing to Destroy *Staphylococcus aureus* in Mechanically Deboned Chicken Meat," *J. Food Sci.*, Vol 57, 1992, pp. 848–851.
[L] Sommers. C. H., Niemira, B. A., Tunick, M., and Boyd, G., "Effect of Temperature on the Radiation Resistance of Virulent *Yersinia enterocolitica*," *Meat Science*, Vol 63, 2002, pp. 323–328.
[M] Kamat, A. S., Khare, S., Doctor, T., and Nair, P. M., "Control of Yersinia enterocolitia in raw and pork products by gamma irradiation," *Int. J. Food Microbiol.*, 36: 1997, pp. 69-76.

X2. CRITERIA FOR ASSESSING IRRADIATION EFFICACY IN CONTROLLING PATHOGENIC BACTERIA, PARASITES, AND SPOILAGE ORGANISMS (see CAC/GL 21-1997 (23))

X2.1 Some local authorities have mandatory upper limits for pathogens, which, if exceeded, render the product unnusable.

X2.2 The criteria for total standard plate count are established by the food producer or food processor based on the end use of the product and any applicable government requirements.

X2.3 Failure to meet the criterion in X2.1 and X2.2 should direct attention to the manufacturing process and the reestablishment, if necessary, of GMPs.

REFERENCES

(1) International Consultative Group on Food Irradiation, *Code of Good Irradiation Practice for Prepackaged Meat and Poultry (to control pathogens and/or extend shelf-life)*, ICGFI Document No. 4, Issued by the Secretariat of ICGFI, Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture, Vienna, Austria 1991.

(2) U.S. Code of Federal Regulations, Title 9, Section 301.2, Washington, DC.

(3) U.S. Code of Federal Regulations, Title 9, Section 381.1, Washington, DC.

(4) National Advisory Committee on Microbiological Criteria for Foods, *Hazard Analysis and Critical Control Point Principles and Application Guidelines*, USDA, Food Safety and Inspection Service, Washington, DC, August 1997 .

(5) U.S. Department of Agriculture, Food Safety and Inspection Service, *Generic HACCP Model for Irradiation*, HACCP-8, Washington, DC, April 1997.

(6) Praveen, et. al., "Susceptibility of Murine Norovirus and Hepatitis A Virus to Electron Beam Irradiation in Oysters and Quantifying the Reduction in Potential Infection Risks," *Applied and Environmental Microbiology*, 2013, 79: pp. 3796-3801.

(7) Espinosa, et. al, "Quantifying the reduction in potential health risks by determining the sensitivity of poliovirus type 1 chat strain and rotavirus SA-11 to electron beam irradiation of iceberg lettuce and spinach," *Applied and Environmental Microbiology*, 2012, 78(4), pp. 988-993.

(8) Food and Drug Aministration, *Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins*, 2nd Ed., Washington, DC,2012.

(9) International Commission on Microbiological Specifications for Foods (ICMSF), *Microorganisms in Foods 5: Characteristics of Microbial Pathogens*, London: Blackie Academic & Professional, ISBN: 041247350X, 1996.

(10) U.S. Code of Federal Regulations, Title 21, Part 110, *Current Good Manufacturing Practices in Manufacturing, Packaging, or Handling Human Food*, Washington, DC.

(11) U.S. Code of Federal Regulations, Title 9, Part 416, *Sanitation*, Washington, DC.

(12) U.S. Code of Federal Regulations, Title 9, Section 381.66, Washington, DC.

(13) U.S. Code of Federal Regulations, Title 21, Section 179.25(d), Washington, DC.

(14) Ehlerman, D., Process Control and Dosimetry in Food Irradiation, *Food Irradiation: Principals and Applications*, Molins, R. A., ed. John Wiley & Sons, New York, 2001, pp. 387-413.

(15) Dosimetry for Food Irradiation, IAEA, Technical Reports Series 409, Vienna, 2002, Online, Available: http://www-pub.iaea.org/MTCD/publications/PDF/TRS409_scr.pdf. 4 March 2016.

(16) Luchsinger, S. E., et al, "Sensory Analysis of Irradiated Ground Beef Patties and Whole Muscle Beef," *Journal of Sensory Studies*, Vol 12, 1997, pp. 105–126.

(17) U.S. Code of Federal Regulations, Title 21, Section 179.26(b), Washington, DC.

(18) Molins, R. A., ed., "Irradiation of Meat and Poultry," *Food Irradiation: Principles and Applications*, Chapter 6, Wiley-Interscoence, New York, 2001, pp. 131-191.

(19) Dubey, J. P., and Thayer, D. W., "Killing of Different Strains of *Toxoplasma gondii* Tissue Cysts by Irradiation Under Defined Conditions," *J. Parasitol*., Vol 80, 1994, pp. 764–767.

(20) Dubey, J. P., Thayer, D. W., Speer, C. A., and Shen, S. K., "Effect of Gamma Irradiation on Unsporulated and Sporulated *Toxoplasma gondii* Oocysts," *Int. J. Parasitology*, Vol 28, 1998, pp. 369–375.

(21) Brake, R. J., et al, "Destruction of *Trichinella spiralis* by Low-Dose Irradiation of Infected Pork," *J. Food Safety*, Vol 7, 1985, pp. 127–143.

(22) King, B. L., and Josephson, E. S., eds., "Action of Radiation on Protozoa and Helminths," *Preservation of Food by Ionizing Radiation*, Vol III, CRC Press, Boca Raton, FL, 1983, pp. 245–267.

(23) Farkas, J., "Decontamination, Including Parasite Control, of Dried, Chilled, and Frozen Foods by Irradiation," *Acta-Alimentaria*, Vol 16, 1987, pp. 351–384.

(24) Luchsinger, S. E., et. al., "Sensory Analysis and Consumer Acceptance of Irradiated Boneless Pork Chops," *J. Food Sci.*, 61(6), 1996, pp. 1261-1266.

(25) Dickson, J. S., "Radiation Inactivation of Microorganisms," *Food Irradiation: Principals and Applications*, Molins, R. A., ed. John Wiley & Sons, New York, 2001, pp. 23-35.

(26) U.S. Department of Agriculture-Agricultural Research Service, Pathogen Modeling Program Version 7.0, 2012, Available from Dr. Lihan Huang, Eastern Regional Research Center, 600 East Mermaid Lane, Wyndmoor, PA 19038.

(27) U.S. Code of Federal Regulations, Title 21, Section 179.26(c), Washington, DC.

(28) McLaughlin, W. L., Boyd, A. W., Chadwick, K. H., McDonald, J. C., and Miller, A., *Dosimetry for Radiation Processing*, Taylor and Francis, London, New York, Philadelphia, 1989.