TECHNICAL REPORTS SERIES NO. 481

Manual of Good Practice in Food Irradiation

Sanitary, Phytosanitary and Other Applications

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MANUAL OF GOOD PRACTICE IN FOOD IRRADIATION

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TECHNICAL REPORTS SERIES No. 481

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SANITARY, PHYTOSANITARY AND OTHER APPLICATIONS

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FOREWORD

Irradiation is one of the few food technologies that can maintain food quality and address food safety and security problems without significantly affecting a food's sensory or nutritional attributes. Irradiation has the ability to slow ripening, inhibit sprouting in bulbs and tubers, control spoilage and food borne pathogenic microorganisms as well as prevent the spread of invasive insect pests (as a quarantine treatment for fresh produce making any associated insects incapable of reproducing and therefore unable to colonize new territory). The process does not raise food temperatures, leaves no harmful residues and can be applied to packaged food, thus limiting the chances of re-infestation or re-contamination.

The quantities of foods that are irradiated are growing each year, mainly in the Asia and Pacific region and in the Americas. The majority of these foods are treated by gamma irradiation in multipurpose facilities that also serve other commercial sectors and are mostly used to sterilize medical devices, to improve the microbial quality of pharmaceutical and cosmetic ingredients and packaging or to modify the properties of materials. It is expected that more food will be irradiated in the future. As it becomes more economically viable, the number of facilities that specialize in irradiating food may increase. Machine sources (electron accelerators and X ray machines) are expected to become predominant over time.

Sanitary applications of irradiation, such as the reduction of the microbial load in spices and herbs or the inactivation of pathogens in products of animal origin, had been the most common applications of food irradiation until fairly recently. Another application has now emerged as a commercial treatment: the use of irradiation as a quarantine measure in order to prevent the spread of insect pests (e.g. fruit flies) which may otherwise take advantage of an increasingly globalized food supply chain system to spread to new areas and affect agricultural production. This commercial use of these phytosanitary applications has now reached a significant scale. In 2014, around 22 000 tonnes of irradiated fresh produce such as fruit and vegetables were marketed in Australia, New Zealand and the United States of America, coming from various countries of the Asia and Pacific region and Mexico.

This publication aims to help operators of irradiation facilities to appreciate and improve their practices and also to provide detailed, yet straightforward, technical information for stakeholders such as food regulators, manufacturers and traders, who also need to understand 'good practice'. Ensuring that the irradiation process will consistently deliver the expected result is essential for the correct application of the technology and will help to inspire stakeholder, and ultimately consumer, confidence in irradiated food.

This publication is the result of a collaborative effort by the participants of the IAEA Regional Technical Cooperation Project RAS 5057 Implementing Best Practices of Food Irradiation for Sanitary and Phytosanitary Purposes. Originally drafted by an independent expert with extensive experience in the commercial operation of irradiation facilities and quality systems based on ISO standards, this publication was then extensively reviewed, discussed, developed and agreed upon during meetings held in Jeongeup, Republic of Korea, from 22 to 26 October 2012, and finalized in Shanghai, China, from 5 to 11 May 2013.

The IAEA would like to thank all those involved for their valuable contributions to this publication, in particular P. Roberts (New Zealand). The IAEA officers responsible for this publication were Y. Hénon and C. Blackburn of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture.

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1. INTRODUCTION

1.1. BACKGROUND

Irradiation is generally defined as the exposure of a substance to radiation of various frequencies. In this publication, food irradiation is the process in which a product or commodity is exposed to ionizing radiation to improve its safety and to maintain its quality. During irradiation, energy is transferred from a source of ionizing radiation into the treated product. Among the irradiation process parameters, the most important is the amount of ionizing energy absorbed per unit mass of the target material, which is termed 'absorbed dose' or simply 'dose'.

Although it is little known by the general public, the irradiation process is used on a wide commercial scale across the world to enhance polymers and to sterilize single-use medical devices. The technology is also used to maintain the quality of food, improve its microbiological safety or reduce waste. The Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture estimates that the quantity of food irradiated in 2013 was approximately 700 000 tonnes.

One of the most significant changes in the radiation processing industry since 1995 has been the adoption of quality assurance procedures. ISO 9001:2008, Quality Management Systems: Requirements [1], a standard of the International Organization for Standardization (ISO) which sets out the requirements of a quality management system, has become a universal reference. For the radiation sterilization of healthcare products, many irradiation facilities across the world are now certified to ISO 11137-1:2006, Sterilization of Health Care Products: Radiation (Part 1) [2], which contains the requirement for the development, validation and routine control of irradiation processes. For food irradiation, a similar standard — ISO 14470:2011, Food Irradiation: Requirements for the Development, Validation and Routine Control of the Ionizing Radiation Process Used for the Treatment of Food [3] — was developed and published for the first time in 2011. It builds on the international standards for food irradiation and a code of practice for food irradiation facilities that are enshrined in the Codex Alimentarius standards and guidelines, which underpin international trade. Understanding the requirements of such standards is not easy for non-specialists. In addition, the standards state what must be done but not how it must be done and an appreciation of how practices can best meet the standards can be demanding for non-specialists and specialists alike. It is recognized that the degree of implementation of quality management systems can be quite different in developed and developing countries. This difference sometimes results in a barrier for irradiated foods that are, or can be, the object of international trade.

Irradiation cannot be used as a substitute for good manufacturing practice. Primary food production should still be managed in a way that ensures that food is safe and of suitable quality for human consumption. Compliance with the Codex Alimentarius General Principles of Food Hygiene [4] and additional commodity specific codes of hygienic practice requires producers to identify hazards and to implement measures to protect food sources and control plant and animal health.

Food and agricultural products may be irradiated for sanitary, phytosanitary or other purposes. Phytosanitary measures relate to the health of plants and include preventing the introduction or spread of regulated pests. This may be realized by triggering a certain response in the targeted pests (e.g. increasing mortality), preventing successful development (e.g. no emergence of adults), inability to reproduce (e.g. sterility) or inactivation (rendering microorganisms incapable of development). The treatment may be performed in the importing country or prior to export, in which case the regulatory requirements of the importing country apply.

Sanitary measures include applications based on the lethal effects of irradiation on:

(a) Microorganisms, such as those causing foodborne disease, reducing storage time or shelf life, or contaminating products to an unacceptable level for the intended use;
(b) Parasites, such as the helminths that can infest carcasses or protozoa present in fresh cut vegetables;
(c) Insects that cause post-harvest losses.

Other applications are based on the physiological effects of irradiation on plants such as:

— Inhibition of sprouting;
— Delayed senescence;
— Delayed ripening.

Table 1 shows the different applications of irradiation to food and the indicative minimum dose for each purpose.

Historically, sanitary applications of food irradiation have been comprehensively addressed by international and national regulations. The principal standard from an international perspective has been the Codex Alimentarius General Standard for Irradiated Foods [5], and most national authorities that have approved the process of food irradiation will have established comprehensive local regulations and controls.

TABLE 1. APPLICATIONS OF IRRADIATION TO FOOD AND INDICATIVE DOSE RANGE

Indicative dose range (kGy)	Effects	Examples
0.1–1	Sprouting inhibited	Potatoes, onions, garlic and yams
	Ripening delayed	Banana and papaya
	Insects unable to reproduce (phytosanitary treatment)	Fresh produce
	Insects killed	Dried fish, dried fruit and legumes
	Parasites inactivated (helminths and protozoa)	Meat products, fresh fruit and vegetables
1–10	Number of spoilage organisms reduced	Strawberries
	Shelf life extended	Refrigerated meats and fish, ready-to-eat meals
	Non-sporulating microorganisms inactivated	Refrigerated or frozen meats, fish and seafood, pre-cut fruit and vegetables
	Microbiological contamination reduced	Spices and dried food ingredients
Above 10	Reduce microorganisms to the point of sterility	Hospital diets, emergency rations and food for astronauts

Regulation of irradiation for phytosanitary purposes needs to address fresh produce, such as apples or mangoes, as well as non-food articles, such as timber or flowers. Where phytosanitary treatments overlap with food treatments, the regulations and controls need to recognize national and international requirements for both applications. The principal sources of international regulation in this instance are the International Plant Protection Convention [6] and the Codex Alimentarius General Principles of Food Hygiene [4].

1.2. OBJECTIVE AND SCOPE

By introducing the technical aspects of food irradiation and providing examples of good practice when irradiating food for sanitary, phytosanitary and other purposes, this publication aims to assist operators of irradiation facilities treating food, and producers and traders of food and government officers involved

in the authorization or inspection of irradiation facilities treating food. Guidance provided here, describing good practices, represents expert opinion but does not constitute recommendations made on the basis of a consensus of Member States.

2. IRRADIATION FACILITY LICENCES

Any person or organization intending to build or operate an irradiation facility should notify the national regulatory authority for radiation safety and control of radiation sources, and should submit an application for authorization from the regulatory authority for siting, design, construction, acquisition, storage and operation of the irradiation facility (see IAEA Safety Standards Series No. SSG-8, Radiation Safety of Gamma, Electron and X Ray Irradiation Facilities [7]). Any subsequent modification that may have implications on radiation safety should also be made only after receiving approval from the regulatory body.

The operating organization is responsible for the safety of the facility and for operating the irradiation facility in accordance with the national regulatory requirements and radiation safety standards. In accordance with SSG-8 [7], the facility should, among other things:

(a) Have personnel qualified in radiation protection matters, including a radiation protection officer;
(b) Conduct safety assessments;
(c) Conduct periodic verifications of safety;
(d) Have a radiation protection programme in place.

Inspections by other governmental bodies may also verify compliance with fire safety rules, conventional work safety standards and, increasingly, protection against malevolent or terrorist acts.

An increasing number of irradiation facilities have voluntarily implemented quality systems using standards published by ISO as a reference and requested third parties to certify that they comply with these standards. The standards include those introduced in Section 1, ISO 9001:2008 [1] and ISO 14470:2011 [3], and also:

— ISO 13485.2, Medical Devices: Quality Management Systems — Requirements for Regulatory Purposes [8];
— ISO 14001:2015, Environmental Management Systems: Requirements with Guidance for Use [9];

In facilities where food is irradiated, a licence allowing the treatment of food needs to be obtained from the relevant food authority. The authority that oversees irradiation for sanitary purposes will generally not oversee phytosanitary treatments, for which a licence also needs to be obtained from the national plant protection organization (NPPO).

The accreditation of an irradiation facility is particularly important for phytosanitary treatments, as live insects may still be present after the irradiation treatment. The detection of live insects does not represent a failure in the treatment, as sterility or non-emergence is often the required outcome. On-shore inspection of irradiated commodities for treatment effectiveness is indeed impractical. The NPPO inspects the irradiation facility before any phytosanitary treatment can be performed, and if the requirements are met, a certificate of approval for a limited period will be issued. A specimen of certificate of approval issued by the United States Department of Agriculture is given in Fig. 1.

For products irradiated off-shore, States have different policies regarding the tasks entrusted by the NPPO of the importing country to the NPPO of the exporting country. While the initial and renewal accreditations of the irradiation

FIG. 1. Example of the Certificate of Approval (courtesy of United States Department of Agriculture).

facilities are performed by the NPPO of the importing country, the control of the irradiation treatments can be delegated to the NPPO of the exporting country.

3. CHARACTERIZATION OF IRRADIATION FACILITIES

3.1. DESIGN

3.1.1. Layout

An irradiation facility is essentially a warehouse that contains an irradiator (see Fig. 2). The irradiator is composed of a bunker, in which products are exposed to a source of ionizing radiation. In electron beam and X ray irradiators, switching off the power supply stops the emission of the beam. In gamma irradiators, emission of gamma rays cannot be stopped, so the source needs to be placed into a pit (dry storage) or at the bottom of a pool (wet storage) to stop product irradiation.

FIG. 2. Irradiation plant (courtesy of Mevex).

The thickness of the bunker walls is such that it is safe to be in immediate proximity outside the irradiator where irradiation takes place. In continuous irradiators, there needs to be a maze (or labyrinth): a passage linking two areas that is designed to follow an elaborate path so that no radiation originating in one area can reach the other area without undergoing at least one reflection or scattering off the passage wall. Products can thus enter and leave the irradiator without having to interrupt the irradiation process. In batch irradiators, a maze is not needed, since irradiation is interrupted while the products are taken in and out of the irradiation chamber. In some batch models, packaged products to be irradiated are lowered in a 'bell' to the bottom of a pool where a radiation field is created by fixed radioactive sources.

3.1.2. Product segregation and storage

To avoid accidental mixing and to eliminate confusion between irradiated and non-irradiated products, parts of the plant for the treated and untreated products should be segregated (see Fig. 3). When the purpose of the treatment is insect control, segregation decreases the risk of post-treatment re-infestation. Even if it may help to distinguish between irradiated and non-irradiated products, the use of radiation sensitive indicators affixed to process loads and changing colour upon irradiation is not a proper measure of product segregation.

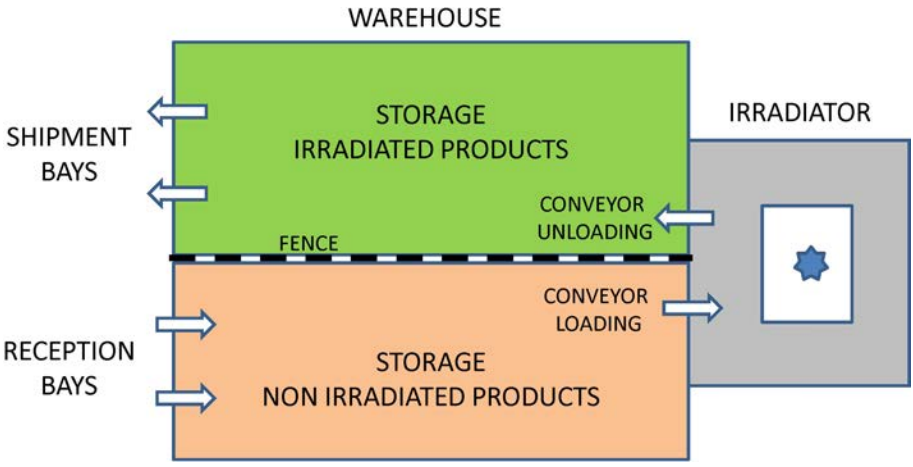


FIG. 3. Typical layout of an irradiation facility.

Physical segregation is usually achieved by placing a fence between the non-treated products and treated products areas. The fence should be high enough and continuous to prevent products passing from one side to the other. There should also be a minimum space of one metre between treated and untreated goods. If doors connect the two areas, it should be possible to open them only under controlled conditions.

FIG. 4. Adjustable dock seal.

In some facilities, segregation is obtained by using two storage levels or by using a layout that provides single direction movement of products, with no possibility for the treated products to be near the untreated products. Within each area, it is usual to create zones for the different types of product treated at the facility. Food products are separated from other products (medical, cosmetics or empty packaging). Products with strong odours should be near the most ventilated parts of the warehouse. Conspicuous signage should indicate the types of product allowed in each zone.

Controlled temperature storage is required where refrigerated and frozen products are treated. Where the power supply is not stable, a backup generator should be available.

Where products are treated for phytosanitary purpose, there may be a need for holding rooms secured at all times to prevent re-infestation of treated products with untreated products and entry of unauthorized personnel. Extra fixtures are required to prevent flying insects from entering, such as double doors, air curtains, screens on windows and other openings, and loading dock seals. While trucks are loaded or unloaded, dock seals such as the one shown in Fig. 4 limit the possibilities of insects entering the warehouse.

3.2. RADIATION SOURCES

The Codex Alimentarius General Standard for Irradiated Foods [5] includes the following ionizing radiations for the treatment of food:

(a) Gamma radiation from ^{137}Cs or ^{60}Co;
(b) Accelerated electrons (forming electron beams) with a maximum energy of 10 MeV[1];
(c) X rays with a maximum energy of 5 MeV.

Radiation processing with X rays up to 7.5 MeV is permitted in the United States of America [10]. The difference in nature of these types of ionizing radiation results in different capabilities to penetrate into matter (see Table 2).

[1] MeV: Million electronvolts. The electronvolt (eV) is a unit of energy, where 1 MeV is approximately 1.6×10^{-13} J.

TABLE 2. DIFFERENT TYPES OF IONIZING RADIATION AND PENETRATION

	Gamma radiation and X rays	Accelerated electrons
Comprised of	Photons	Electrons
Mass	None	Yes
Electric charge	None	Yes
Penetration	Good/very good	Limited
Consequence	Products of low and medium density can be treated in cartons, drums or pallets	Products of low density can be treated in cartons

To be applicable to any density value, the penetration capability is expressed in g/cm^2. The pattern regarding the point of maximum dose and the absorption of the energy differs between accelerated electrons and photons (see Fig. 5). The penetration of 10 MeV electrons is limited, since the electrons deposit their energy over a short depth, with a maximum located after the entrance point (build-up before that point). In the case of photons, the energy is deposited over a longer distance, which will result in a more uniform dose distribution within the treated product. The penetrations of 7.5 MeV X rays and gamma rays are

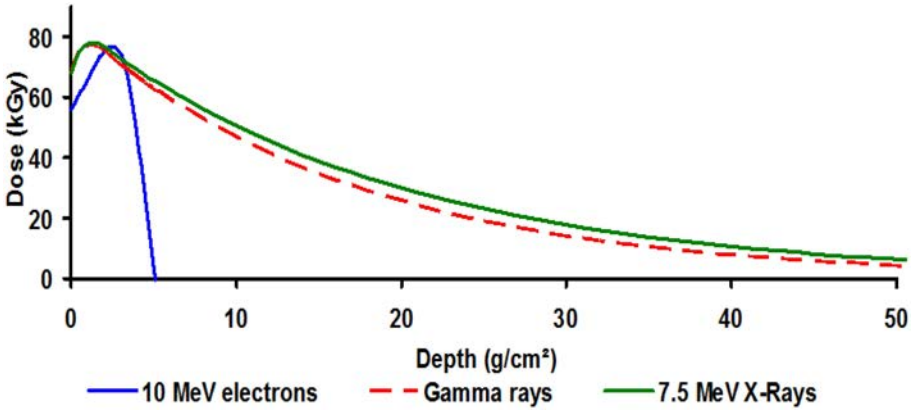


FIG. 5. Compared penetration of ionizing radiation.

comparable, but the higher energy of the X photons will result in an even better uniform distribution of the doses within the treated product.

The differences between these types of ionizing radiation also result in different operational characteristics between the irradiators in which they are used (see Table 3). The dose rate, or quantity of energy emitted per time unit, determines the processing times, and hence, the throughput of the irradiator (i.e. the quantity of products the cab used per time unit).

TABLE 3. OPERATION CHARACTERISTICS OF THE DIFFERENT TYPES OF IONIZING RADIATION

	Human made radioisotope (Co-60 or Cs-137)	Machines using electricity	
Type of radiation	Gamma	Accelerated electrons	X rays
Emission of radiation	Cannot be switched off Isotropic Direction cannot be controlled	Can be switched off Unidirectional Direction is controlled (beam)	
Consequence	Non-stop operation (24/7) to optimize source use	Flexible operation schedule A truckload can be processed within hours	
Dose rate (order of magnitude)	kGy/h	kGy/s	kGy/min

3.3. CHARACTERIZATION OF RADIATION SOURCES

The numerous elements that characterize an irradiator should be thoroughly documented.

3.3.1. Gamma irradiators

The first gamma irradiators were built around 1950, and the concept has not changed much since then. A schematic view of a gamma pallet irradiation plant is provided in Fig. 6.

The first characteristic is the type of radionuclide used, which is either caesium-137 (^{137}Cs) or cobalt-60 (^{60}Co). Cobalt-60 is by far the most common source of gamma irradiation and ^{137}Cs is now only found in laboratory facilities.

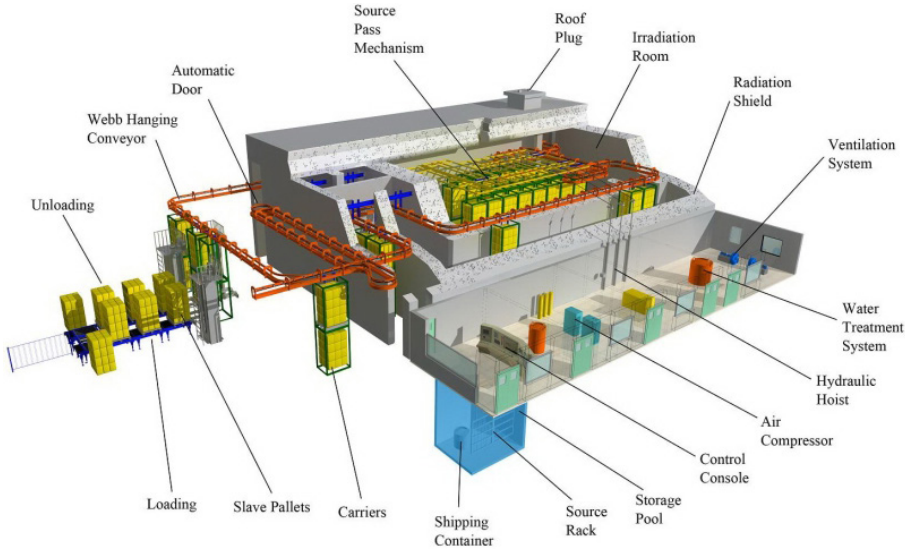


FIG. 6. Pallet gamma irradiator (courtesy of SQHL).

The second characteristic is the activity of the source: that is, the quantity reflecting its strength. This is measured using the SI unit the becquerel (Bq), which is the number of radioactive decays per second, or in curies (Ci), which is the activity of one gram of ^{226}Ra. The use of curies, which is not an SI unit, still prevails in the radiation processing industry. The relationship between the two units is:

$$1\,\text{Ci} = 3.7 \times 10^{10}\,\text{Bq} \tag{1}$$

Since radionuclides continually decay, their activity continually changes. Hence, the activity value needs to be associated with a date. The initial value of the activity given in the source certificates established by the source supplier is to be used as a reference. How the irradiator operator changes the processing times to take the decay into account needs to be clearly established.

The half-life of ^{60}Co is 1925.2 days, which means that at the end of this period the activity is half the initial activity. The activity A after d days of decay can be derived from the initial activity A_0 using the equation:

$$A = A_0 \exp\left\{\frac{-\ln 2 \times d}{1925.2}\right\} \tag{2}$$

The rate of decay is approximately 1% per month, which is far less than uncertainties on routine dosimeters. Consequently, monthly readjustments of the processing times are sufficient to take into account source decay in the adjustment of processing times.

A third characteristic is the mode in which the irradiator operates, which can be continuously or by batch.

The type of container that can be irradiated and how they travel to and from the source are other defining features. Products to be irradiated can be in their usual shipping cartons, in tote boxes or stacked on a pallet that will be transported to and from the irradiator in hanging carriers or on roller bed conveyors. Radionuclides are contained within sealed metallic tubes called 'pencils' that are placed on a metallic rack referred to as the source (see Fig. 7).

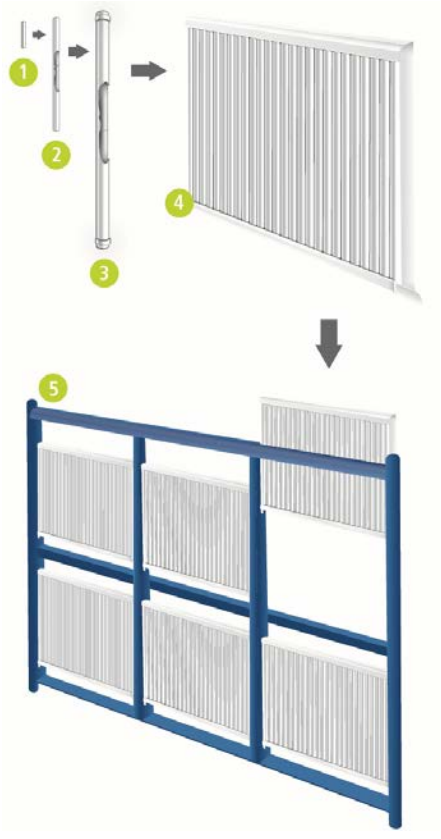


FIG. 7. Composition of a ^{60}Co source rack.

The activity contained in each pencil, the number and dimensions of the pencils and the shape and size of the rack have an effect on the dose distribution in the products. These elements make the source geometry, which needs to be characterized and documented. Each pencil has a unique identification number, and its activity and exact position on the source rack needs to be recorded.

Depending on the respective heights of the source and of the products, gamma irradiators fall into two basic categories: overlapping source or overlapping product (see Fig. 8).

Irradiators with a product overlap design have a higher proportion of the emitted radiation absorbed by the products, but a level switch of product at mid-exposure is required to improve the vertical dose uniformity.

In single pass irradiators, a single file of products travel in a symmetric pattern on each side of the source. The radiation having crossed the products is wasted in the walls of the bunker (see Fig. 9). However, there is little attenuation effect between the products being irradiated.

In multiple pass irradiators, more of the energy emitted by the source is absorbed by the products. However, the dose received at a given position by a given product depends on the quantity and density of other products between this product and the source. The design may allow products to take all of the passes, the two innermost (passes 3+4), the two outermost (passes 1+6) or two passes on each side. Using only the outermost passes is a way to reduce the dose uniformity ratio as compared to using passes closer to the source.

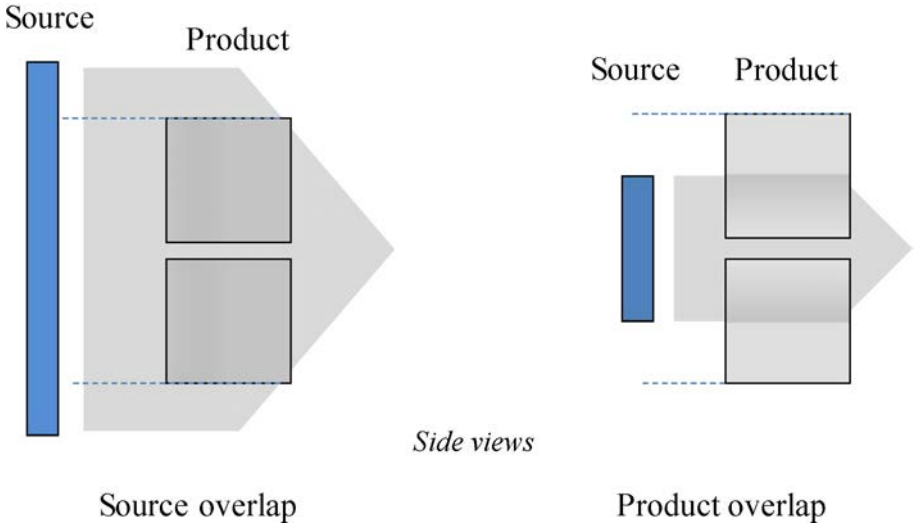


FIG. 8. Source overlap versus product overlap.

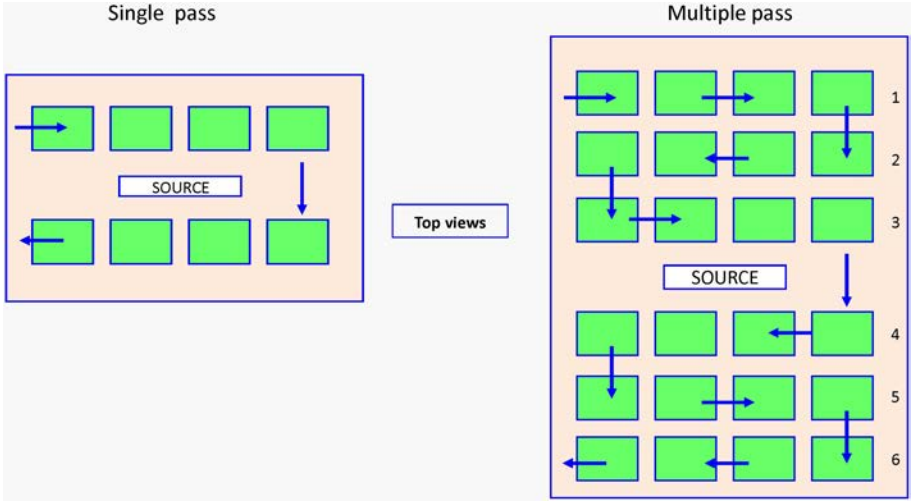


FIG. 9. Examples of single pass and multiple pass gamma irradiators.

The position of the gamma source is usually indicated by warning lights placed on the control panel and at the points of entry of personnel and products. There are generally three states:

(a) The source rack is in its normal safe storage position. The irradiation time counter is stopped.
(b) The source rack is in its normal irradiation position, which is most often detected by a proximity switch. The exposure time is counted only when the source is in that position.
(c) When the source rack is not in any of these positions, in normal circumstances it is travelling between the two. The irradiation timer is then stopped but some product irradiation does take place during the source transit and its potential impact on the cumulated dose (transit dose) should be assessed.

Gamma irradiators work on the fail-safe principle. Any abnormal occurrence (e.g. power outage, jammed conveyor, fire alarm or timer failure) causes the source to return to the safe storage position and the irradiation time count to cease. In most wet panoramic irradiators, the source rack goes back to the bottom of the storage pool by gravity, at a speed that can be controlled by the rate of air let out of a pneumatic cylinder.

3.3.2. Electron beam and X ray irradiators

The maximum energy of the electrons or photons that can be produced, expressed in MeV, determines the penetration power of an electron beam irradiator (see Fig. 10). A number of reference publications, such as the Codex Alimentarius General Standard for Irradiated Foods [5], restrict the energy of accelerated electrons to levels below the energy at which short lived radioisotopes would be created. While 10 MeV is an undisputed limit for electron beams, the 5 MeV limit for X rays, set when the technology was not yet commercially used, might be reconsidered in the future — as it has already been in the United States of America, where it is now 7.5 MeV [10]. At higher energies, the X ray conversion rate is higher, resulting in a higher quantity of product treated per time unit (throughput).

The second characteristic is the beam current, expressed in milliamperes (mA), for industrial machines. The beam current determines the dose rate and potential throughput. The dose delivered (D) is proportional to the beam current (I) and inversely proportional to the velocity of the product (v). This can be expressed as $D = k\ (I/v)$, where k is a coefficient that varies with, among other things, the distance between the product and the point of emergence of the beam, the scan width and the geometry of the transport system. Accelerator power is the product of electron energy and beam current. For example, the power of a 5 MeV accelerator at 30 mA is 150 kW.

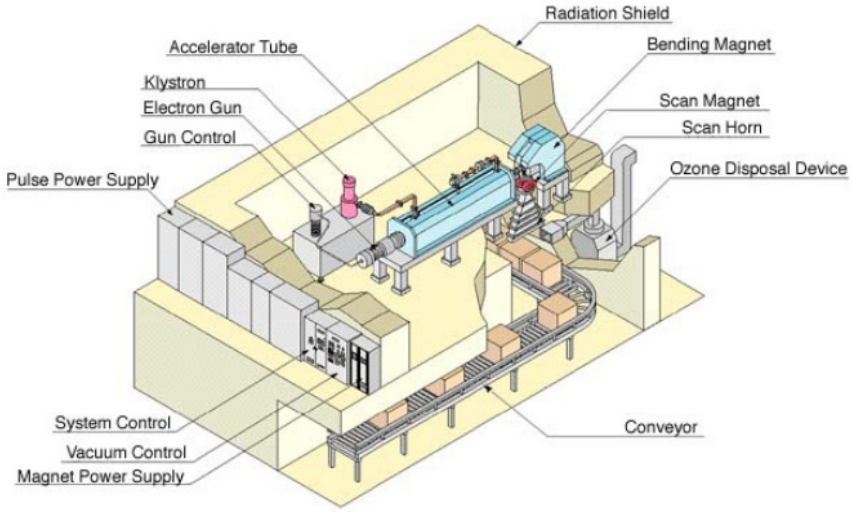


FIG. 10. Electron beam irradiator.

The electron beam spot profile and the scan width (see Fig. 11) need to be known to ensure a proper dose distribution pattern on the surface of the treated product. The scan width may be defined as the width at a defined fractional level (e.g. 90%).

In X ray machines, the impinging electrons are stopped in a converter made of tungsten, tantalum or gold. As the electrons decelerate, energy is conserved and part of their kinetic energy is converted into photons (bremsstrahlung). The remaining energy is converted into heat. The converter material, its thickness and geometry affect the conversion efficiency and the self-absorption inside the converter.

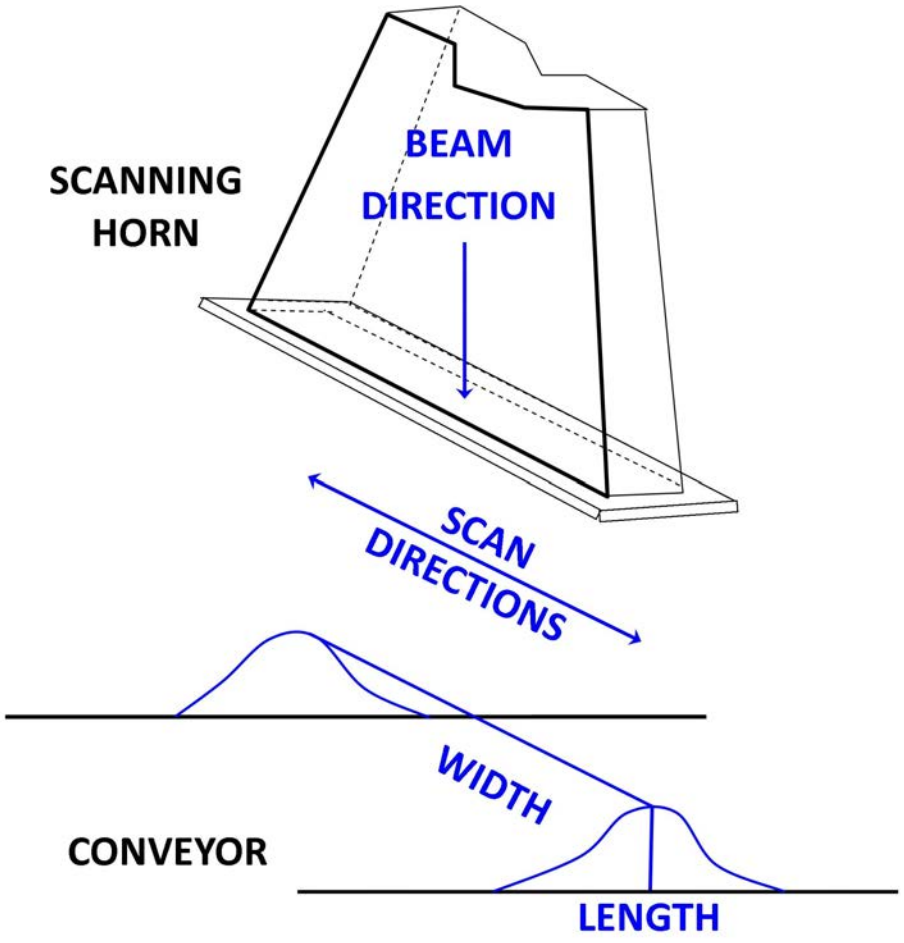


FIG. 11. Scanning characteristics.

Other characteristics include the means to indicate that the beam and the conveyor are operating, the means of ceasing irradiation if any failure of the conveyor occurs or the means of ceasing conveyor movement if any fault in the beam occurs. Light indicators in the control room and in critical locations such as maze entrances as well as displays on the control panel are generally used to indicate that the facility is operating and that the beam is on. Supervision systems monitor the treatment parameters, principally the beam current and the conveyor speed, to verify that they are within tolerances. When a deviation occurs, the system may react by stopping, starting an alarm and then generating a report identifying the products that were affected.

3.4. EQUIPMENT

After the radiation generator, the conveyor is the most important piece of equipment of an irradiator. The most common problem that will cause an unscheduled process interruption is usually a malfunction of the conveyor.

While electron beam machines irradiate cartons in rapid succession one at a time, gamma and X ray irradiators can simultaneously treat many pallets or many irradiation containers. The throughput and the dose distribution largely depend on the dimensions of the carriers or trays that the conveyor transports, as well as its minimum and maximum speed. The doses to be delivered are controlled by the total irradiation time, which is controlled by the conveyor speed; hence the criticality of this parameter.

The first programmable logic controllers appeared in irradiator control systems in the 1980s, and since then personal computers have been introduced as human–machine interfaces to assist functions such as irradiation sequence scheduling and dosimeter readings or to maintain databases. Software now plays a major role in monitoring and controlling the process. The vast majority of software problems are traceable to errors made during the design and development process. Because of their critical functions, software needs to be developed in accordance with a quality management system and documentary evidence that the software meets its design intention. The activities that need to be performed aim at answering two questions:

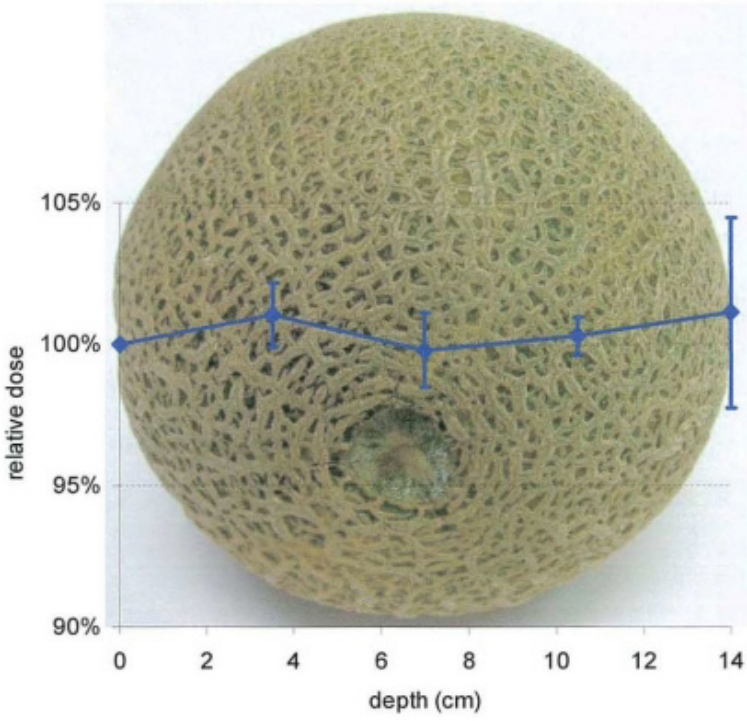
(a) Was the software built right? These are the verification activities.
(b) Was the right software built? These are the validation activities.

The processes of software engineering are described in ISO/IEC 12207:2008, Systems and Software Engineering: Software Life Cycle Processes [11].

4. DOSIMETRY

4.1. DOSE

The absorbed dose, or dose, is the quantity of ionizing radiation energy imparted to a unit mass of a specified material. The SI unit of absorbed dose is the gray (Gy), where 1 Gy is equivalent to the absorption of 1 J/kg. It is the quantity that is used both to specify the irradiation process and to control it. Irradiation does not deliver one single dose throughout a product but a continuum of doses (see Fig. 12).



Note: Average of three dose profiles after double sided gamma irradiation in an experimental irradiator where dose distribution is more uniform than in a commercial irradiator.

FIG. 12. Dose distribution in a single rock melon.

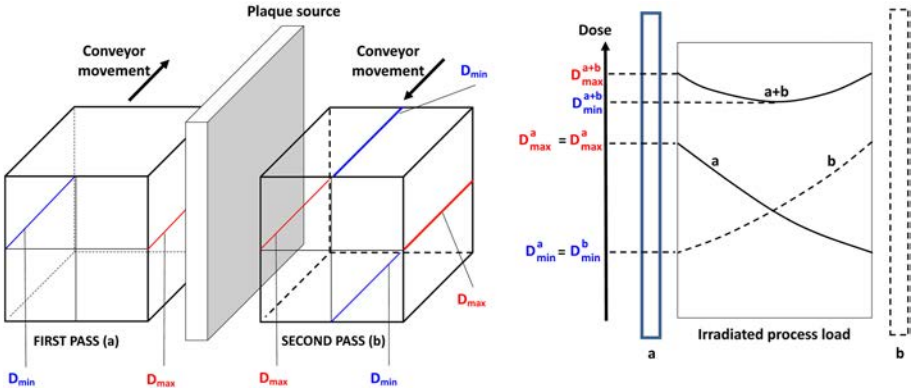


FIG. 13. Regions (hatched) of maximum and minimum doses in a rectangular product gamma irradiated on two sides and distribution of cumulative doses (a + b).

The dose range is broader in a commercial load such as a pallet than in a single item. The spread of doses, or dose range, increases as the size or density of the treated material increase. An accurate measurement of absorbed dose in a consignment is critical for determining and monitoring efficacy and guaranteeing consumer safety. Applying the specified minimum dose is especially critical in phytosanitary treatments, where it guarantees that the pests that may survive irradiation are not viable.

Typical dose distribution after electron beam irradiation differs from dose distribution after gamma or X ray irradiation (see Figs 13 and 14).

Figure 14 shows the regions (hatched) of maximum and minimum doses for a rectangular product of homogeneous density after a double-sided electron beam irradiation (top and bottom) and the distribution of cumulative doses. The pattern will vary with density.

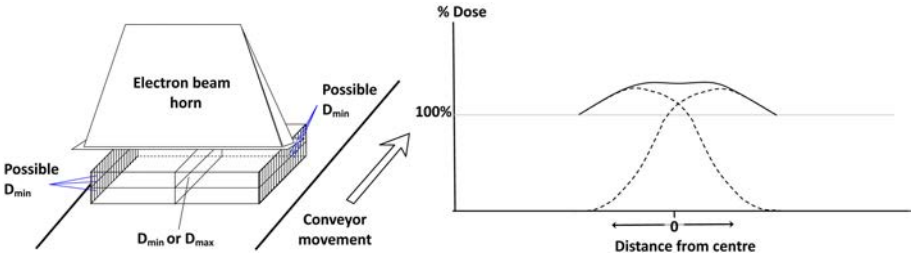


FIG. 14. Dose distribution in a rectangular product after top and bottom electron beam irradiation.

4.2. DOSIMETRY SYSTEMS

A dosimetry system includes dosimeters, the instruments that measure the absorbed doses, the procedures and the standards.

A dosimeter is a device with a reproducible, measurable response to irradiation which can be used to measure the absorbed dose in a given system. In other words, a dosimeter is a material that is affected by irradiation in a consistent and measurable way. This material, or item, is then used to calculate the amount of ionizing radiation to which the product has been exposed. So it can be read or measured and expressed as absorbed dose.

There are different levels of dosimetry systems with a growing level of uncertainty:

(a) Primary dosimetry used by national standards laboratories, which is based on calorimeters and ionization chambers and is the only system that does not require calibration.
(b) Reference dosimetry, which needs to be calibrated against a primary standard and can be used to calibrate other dosimeters.
(c) Transfer dosimetry, which is a bridge between an accredited calibration laboratory and an irradiation facility in order to establish traceability for that facility. Most reference dosimetry systems except calorimeters can be used as transfer dosimetry systems.
(d) Routine dosimetry used in the irradiation facility for dose mapping and routine control.

The selection and use of specific dosimetry systems in a given application is justified by taking into account the dose range, the type of radiation, the influence of factors such as dose rates, the required level of uncertainty and the required spatial resolution. Guidance is provided in standard ISO/ASTM 51261:2013, Practice for Calibration of Routine Dosimetry Systems for Radiation Processing [12]. Table 4 provides examples of dosimetry systems (for phytosanitary applications, see ASTM F1355-06(2014), Standard Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment [13]).

TABLE 4. EXAMPLES OF DOSIMETRY SYSTEMS THAT CAN BE USED FOR GAMMA, ACCELERATED ELECTRON AND X RAY

Dosimeter	Dose range (Gy)	Dose rate range (Gy/s)	Main factors influencing readings
Alanine	$1–10^5$	$<10^8$	Temperature +0.25% per °C
CTA FTR 125 Fuji	$10^4–3 \times 10^5$	$(3–4) \times 10^7$	Temperature +0.5% per °C
Far West Technology FWT 60	$10^3–2 \times 10^5$	$<10^{13}$	Dose, temperature and relative humidity
GEX B3	$10^3–10^5$	$<10^{13}$	Dose, temperature and relative humidity
Harwell Perspex (Red, Amber)	$10^3–5 \times 10^4$	$<7.5 \times 10^3$	Dose and temperature

4.3. UNCERTAINTY IN DOSE MEASUREMENT

Measurements are subject to uncertainty, and each measured value can be accompanied by a statement of the associated uncertainty. This uncertainty characterizes the dispersion of the values attributed to a measured quantity. Causes of uncertainty include:

— Differences in conditions of calibration and routine use;
— Variations in environmental conditions before, during and after irradiation;
— Location of routine dosimeter;
— Variations in exposure to the radiation source;
— Variations in irradiation time;
— Intrinsic variation between individual dosimeters;
— Coefficient between reference dosimeter used routinely, and minimum and maximum doses;
— Measurement of thickness or weight of individual dosimeters;
— Variations in readout equipment;
— Variations in environmental conditions during measurement;
— Uncertainty in the dose of reference dosimeters during calibration;
— Fit of data to a calibration curve.

Knowing the uncertainty is a requirement of ISO standards related to radiation processing, such as ISO 14470:2011 [3]. The value of uncertainty is needed for:

(a) Interpretation of dose mapping data when establishing the significance of small variations in measured dose, and identification of low and high dose regions;
(b) Interpretation of routine dosimetry data when establishing the origin of observed dose variability;
(c) Establishment of routine operating parameters to ensure dose delivery within defined confidence limits.

Uncertainty should also be considered for the number of decimal places used when stating a dose. For example, with dosimeters with an uncertainty of 4%, it does not make sense to use more than one decimal place for doses of several kilograys.

Establishing the uncertainty is not easy and requires a good working knowledge of statistics. Standard ISO/ASTM 51707:2015, Guide for Estimation of Measurement Uncertainty in Dosimetry for Radiation Processing [14], and Guidelines for the Calibration of Routine Dosimetry Systems for use in Radiation Processing [15] of the UK National Physical Laboratory provide guidance on estimating dosimetry uncertainties.

4.4. DOSIMETRY SYSTEM CALIBRATION

Each new batch of dosimeters needs to be calibrated to national or international standards and for the particular measuring device used at the facility, a specific calibration curve with the absorbed dose as a function of the measurement should be constructed. Dosimeters also need to be recalibrated after a predetermined period. Reference should be made to the relevant ISO/ASTM standards regarding various types of dosimeter and Guidelines for the Calibration of Routine Dosimetry Systems for Use in Radiation Processing [15].

A sufficient number of dose points throughout the recommended dose range of the dosimeters should be used so that the intervals are not too large. There are two basic methods to calibrate dosimeters:

(a) Irradiation of reference dosimeters purchased from a national or international laboratory together with routine dosimeters in the plant;
(b) Irradiation of routine dosimeters in the irradiator of a reference laboratory.

For in-plant calibration using reference dosimeters, there should be at least two routine dosimeters at each dose point, both from the batch in use and from the batch being calibrated, together with a pair of reference dosimeters. The average of the dosimeter readings and the reference pair are used when analysing the data. When returning the irradiated reference dosimeters to the reference laboratory, the irradiation temperature should be provided, as it generally influences the dosimeters.

If the irradiations for calibration are performed at a reference laboratory, several dosimeters from the batch being calibrated should be irradiated at each of the dose values selected throughout the recommended dose range of the dosimeters. When the results have been used to generate a curve showing the dose as a function of the measurement, the curve should be confirmed or adjusted by processing a pair of reference dosimeters, together with a few routine dosimeters from the batch under calibration and a few dosimeters from the batch in use processed at several dose points throughout the range of the dosimeters under calibration. The average of the routine dosimeters is used when analysing the data. These reference dosimeters will address differences in temperature and dose rate between the source in the reference laboratory and the source of the plant.

Acceptance criteria for the curve that is obtained should be set with regard to:

— The difference between readings of the batch in use and the batch that was calibrated, which will impact the processing times;
— The difference between batch that was calibrated and reference dosimeter readings.

For example, if the difference is greater than 5% at any point on the curve, the calibration should be repeated.

Some types of dosimeter (e.g. Perspex) require a post-irradiation stability study because the time elapsed between the end of irradiation and the read-out will influence the result. Other types (e.g. thin film dosimeters) do not require a stability study.

4.5. DOSE MAPPING

Dose mapping is performed by placing dosimeters throughout products, irradiating the products in known conditions and reading the dosimeters values. Further information on the practices used for electron beams and X rays are described in ISO/ASTM 51431:2005, Practice for Dosimetry in Electron Beam

and X Ray (Bremsstrahlung) Irradiation Facilities for Food Processing [16], and for gamma rays in ISO/ASTM 51204:2004, Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing [17]. The objectives are:

(a) To determine the dose distribution throughout the products and in particular where the minimum and the maximum doses are found;
(b) To demonstrate that the products can be treated within the required range;
(c) To assess the variability of the particular process;
(d) To establish the process parameters that will lead to doses within the required range;
(e) To establish how the process will be monitored routinely.

Dose mappings are used during the operational qualification of an irradiation facility — when they are performed with homogeneous material — and during the performance qualification — when they are performed with inhomogeneous material (products to be treated routinely).

A dose mapping is specific to an irradiator, a product path, a load configuration and product characteristics. Any change in these will affect dose distribution and therefore requires dose mapping to be repeated.

4.5.1. Number and placement of dosimeters

Enough dosimeters should be used to obtain statistically significant results. In a process load containing voids or a non-uniform product, dosimeter sets should be placed at locations where variations in composition or density may affect the regions of maximum or minimum dose. Dosimeter films in sheets or strips may also be employed to obtain useful information.

Various systems can be used to assign a unique code to dosimeters used for dose mappings. The code can, for example, be made of three numbers, which are the distances in centimetres from a point of origin in the x, y and z axes. The three numbers can also identify the horizontal layer, a vertical plane and another vertical plane perpendicular to the first one, as shown in Figs 15 and 16.

The total number of dosimeters will depend on the volume of the irradiation container and the information already available from operational qualification and previous dose mappings. Usually, it is considered that any two dosimeters should not be more than 20 cm apart, but if there is sufficient experience, the frequency of dosimeters may be increased in the regions where the minimum and maximum doses are usually found and fewer dosimeters be placed in areas likely to receive intermediate dose. Dose mapping for electron beams should take into account that, due to buildup, maximum doses occur under the surface, inside the product.

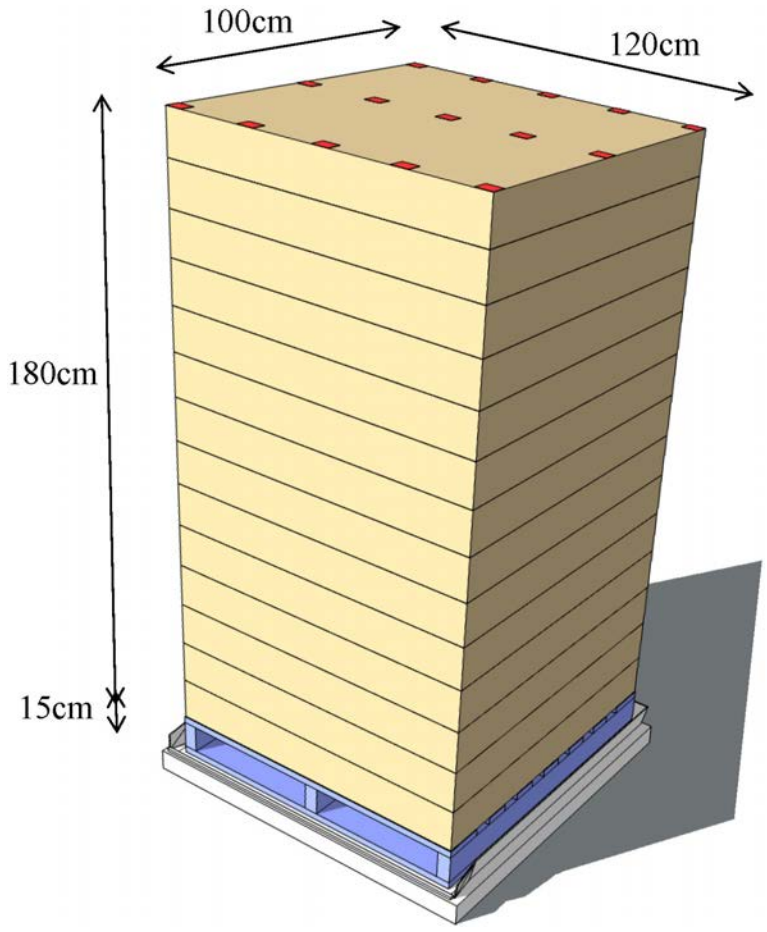


FIG. 15. Load to be irradiated.

4.5.2. Effect of temperature

The response of dosimeters is affected by the temperature during irradiation. For chilled or frozen foods, dose mapping may be performed at the temperature to which the food will be chilled or frozen during actual product processing if the dosimetry system used can be characterized at the intended processing temperature. If this cannot be done, dose mapping may be performed with a simulated product at room temperature. In either case, the parameters when treating chilled or frozen food need to be the same as those used during dose mapping (with the exception of food temperature if dose mapping involved a simulated product at room temperature). Dose mapping of a simulated product

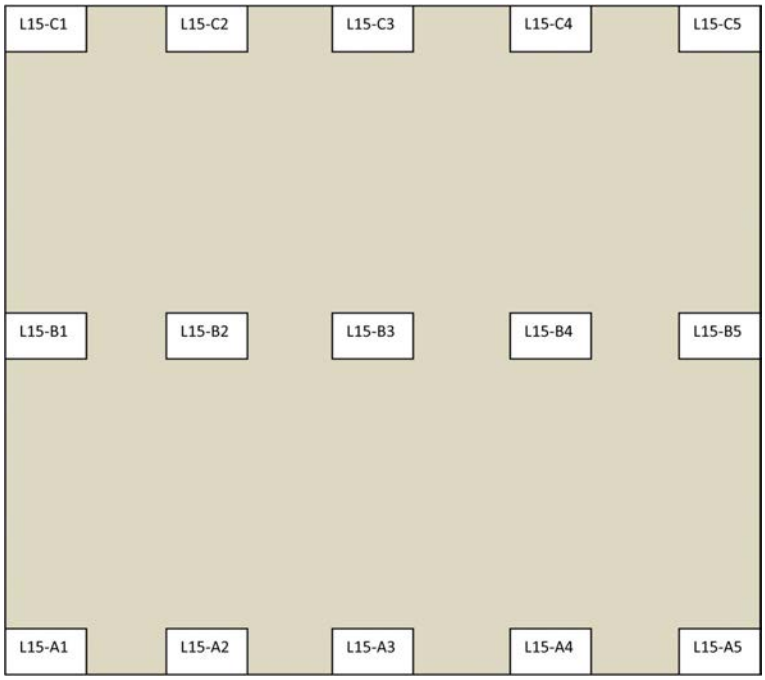


FIG. 16. Placement of dosimeters.

at room temperature should include placing one or more dosimeters at a reference position known to be insulated from temperature changes during processing.

4.5.3. Effect of other products in a gamma irradiator

For gamma and X ray irradiators, dose mapping may be carried out to identify other products that can be processed along with the product being mapped. The effect of the presence of different products of different densities in the irradiator on the dose absorbed by the products needs to be determined to define the different products that can be irradiated together.

4.5.4. Dose variability

Two irradiation containers loaded in the same way, with similar contents and irradiated successively with the same process parameters, will not yield exactly the same dose values. The differences are due to slight variations in the responses of the individual dosimeters, position of the products within the irradiation container (due to shifts in the contents of the process loads during

their movement through the irradiator), position of the containers during irradiation, placement of the dosimeters and uncertainties in dosimeter readings. It is advisable to perform dose mappings at least in triplicate to determine the values of the minimum and the maximum dose. Though the calculated average of the minimum values and maximum values is often used, it is a better practice to use the method described in section 4.4.4 of Ref. [18], which takes into account the standard deviations for the minimum and the maximum doses.

4.5.5. Routine reference dosimeter

When the position of the minimum or maximum dose is inside the products, it is not practical to place dosimeters there routinely. In this case, a common practice is to use a reference dosimeter that is placed on the surface of the load or on the irradiation container in a location that is readily accessible and easily reproducible for the operator (see Fig. 17). For a given load configuration, a given path though the irradiator or given machine settings, the relationship between the reference dosimeter and the minimum and maximum dose is arithmetic and constant. The coefficient needs to be established during dose mapping.

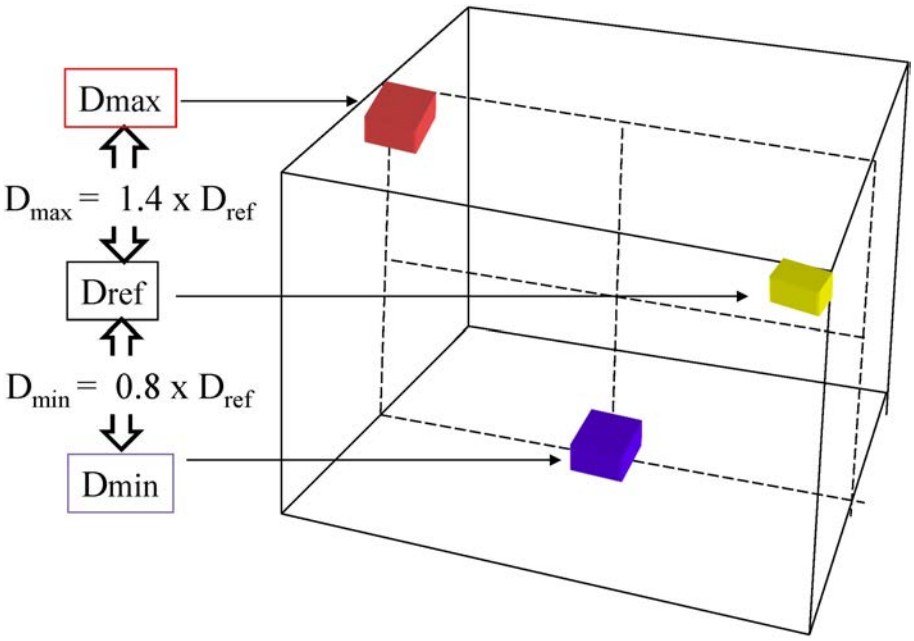


FIG. 17. Relationship between minimum and maximum doses and the dose in the reference position.

Example

The minimum dose is 2.4 kGy, the maximum dose is 4.2 kGy and the dose for the reference dosimeter (D_{ref}) is 3.0 kGy. Then

$$D_{min} = \frac{2.4}{3.0} = 0.8 \times D_{ref}$$
$$D_{max} = \frac{4.2}{3.0} = 1.4 \times D_{ref} \quad (3)$$

If the targeted dose range is 2.0 kGy minimum and 5.0 kGy maximum, routinely the values of D_{ref} will have to be at minimum 2.0/0.8 = 2.5 and at maximum 5.0/1.4 = 3.57, rounded off to 3.5 kGy. Figure 17 shows the relationship between minimum and maximum doses with a dose in the reference position.

4.5.6. Dose exposure time

Following dose mapping, with the dose values corrected with the uncertainties on one hand (see Section 7.2) and with the process parameters on the other hand — essentially the exposure time or the conveyor speed — a relationship can be established. This relationship will be valid for a given configuration only.

Example

The minimum dose that was obtained during dose mapping is 4.0 kGy with a dwell time of 200 min. The uncertainty in the dose is 5% and the specified minimum dose is 3.0 kGy. Then, the operator will target a dose of 3 kGy + 5% = 3.15 kGy. This will require a minimum dwell time of 200 × 3.15/4 = 157.5 min, rounded up to 158 min.

The maximum dose that was obtained is 7.0 kGy for a dwell time of 200 min. The uncertainty in the dose is 5% and the specified maximum dose is 8.0 kGy. The operator will target a dose of 8 kGy − 5% = 7.6 kGy. The maximum dwell time will be 200 × 7.6/7 = 217.14 min, rounded off to 217 min.

The conclusion of the dosimetry report will be that for a specified range of 3.0–8.0 kGy, the dwell time range will be in the range of 158–217 min.

A dose mapping exercise may reveal that the dose uniformity ratio (DUR), which is the quotient D_{max}/D_{min}, is unacceptably large, which means that the dose spread is in a range broader than the specified range. Methods that may improve the DUR include:

(a) Placing fewer products in the irradiation container;
(b) Decreasing the density of the packages by decreasing the quantity of products in them;
(c) Decreasing the dimensions of the packages;
(d) Using attenuators such as metal plaques in the irradiation containers to shield the areas of highest dose;
(e) Placing 'dummy'[2] products where the minimum or the maximum doses are found;
(f) Irradiating more sides;
(g) Increasing source-to-product distance by using only the outer passes in a multiple passes irradiator;
(h) Rearranging source elements on the source rack in gamma irradiators;
(i) Physically modifying the product flow through the irradiation zone in bulk flow irradiators.

However, these methods will generally lower the efficiency of the process and increase the unit irradiation cost.

Dose mapping may not be feasible for products flowing in bulk through the irradiation zone. In this case, minimum and maximum doses should be estimated by using an appropriate number of dosimeters mixed randomly with, and carried by, the product through the irradiation zone. Enough dosimeters should be used to obtain statistically significant results. Theoretical modelling of the maximum and minimum doses may provide additional information.

4.5.7. Dose mapping reports

Dose mapping reports should be very detailed and include:

(a) The characteristics of the load: description, quantities, dimensions and weights of products and packages.

[2] Dummy products are a mass of material with radiation attenuation and scattering properties similar to those of the product to be irradiated. They can also be called phantom material, compensating material or simulated products.

(b) Drawings showing the irradiation container movement and exposure, the loading configuration and the placement of dosimeters (see Figs 15 and 16).
(c) Irradiator operating conditions: beam energy, scan width and conveyor speed for electron beam or activity and dwell time for gamma irradiators.
(d) Conveyor path in gamma irradiators.
(e) Characteristics of other products simultaneously present in the irradiation room for gamma irradiators.
(f) Analysis of raw dose measurements results and assessment of the variability, determination of minimum and maximum dose values, and range of target doses.
(g) Locations of the minimum dose and maximum dose.
(h) Time range for specified and targeted dose ranges.
(i) Coefficients between the value given by the reference dosimeter and the minimum and maximum dose.
(j) Dose limits for the reference dosimeter.
(k) Type, location and frequency of dosimeters to be used routinely.

5. VALIDATION

Validation is similar to what used to be called commissioning and encompasses a series of exercises designed to verify that an irradiation plant meets its installation requirements (installation qualification), operates to its design specification (operational qualification) and will consistently deliver the required process to a given product within predetermined tolerances (performance qualification).

Installation qualification and operational qualification validate the irradiator and are performed by the irradiator operator with the suppliers. They require the integrated application of a set of engineering techniques and procedures to check, inspect and test every operational component of the project, from individual functions, such as instruments and equipment, to complex amalgamations, such as modules, subsystems and systems including IT systems, and comprehensive documentation. It is applicable to all phases of the project, starts before the order is placed and generally ends after the handover of the unit to the operator.

Performance qualification validates the irradiation process for the actual products and is performed by the irradiator operator with the customer and sometimes a regulatory authority such as the national plant protection organization. In the particular case of phytosanitary treatments, validation is essential, as live target organisms may be present after treatment and the only

method to guarantee that the minimum dose has been delivered depends on the reliability of the process.

5.1. IRRADIATOR SPECIFICATIONS DOCUMENTS

Validation requires that certain documents precisely defining the project be established even before the facility is built.

5.1.1. User requirements specifications

In the user requirements specifications (URS), future operators clearly define what they want the new facility to achieve, including performance (throughput, DUR), critical installation parameters and mode of operation. The requirements may be categorized as essential or desirable. The URS are discussed with the potential suppliers and agreed upon before the order is placed. It is a key document on which the final acceptance of the facility is based.

5.1.2. Functional specifications

This document details what the facility and the software will do and all the functions of the equipment. This document is produced by the supplier and can be part of the response to the tender. It is revised as the project is refined, and, once finalized, it is formally approved by the future operator.

5.1.3. Design specifications

The design specifications describe the specifics of how the system will achieve the functional specifications. They contain all the technical details (i.e. dimensions, engineering specifications, power and rate) as well as drawings.

Each of the above documents established during the design phase is used for verification at the different validation stages after the facility has been built (see Fig. 18).

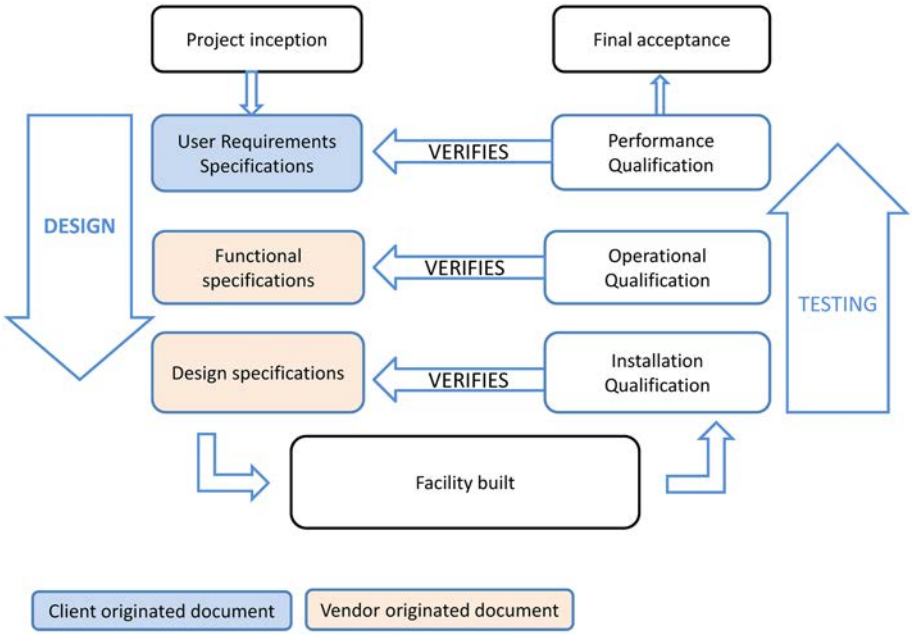


FIG. 18. Relationship between specifications documents and validation steps.

5.2. INSTALLATION QUALIFICATION

Installation qualification needs to demonstrate that the irradiator, the ancillary equipment and measurement devices are delivered and installed in accordance with the specifications. This is based on verifications and tests. Measuring instruments should be calibrated and shown to work within the specifications. Equipment and instruments should be labelled and the facility signage should be in place.

Before installation qualification starts, a protocol with acceptance criteria should be established by the irradiator operator and possibly the suppliers. At the end of installation qualification, the complete documentation should be available, including:

(a) Layout, drawings, piping and instrumentation diagrams;
(b) Detailed description, operation manual and maintenance manual for all equipment and instruments;
(c) Software validation and verification documents [19] and operation manual;

(d) Certificates from the various suppliers;
(e) Procedures to test and operate the equipment and to calibrate instruments;
(f) Reports showing that equipment and instruments work to specifications;
(g) Reports of modifications and subsequent re-testing made during installation, since there is usually some troubleshooting at this stage.

The information generated during installation qualification needs to be reviewed and the outcome of the review recorded.

5.3. OPERATIONAL QUALIFICATION

The purpose of operational qualification is to demonstrate that the installed irradiator operates according to specifications and is capable of delivering the specified processes within tolerances. Before operational qualification starts, all instruments used for monitoring, controlling and recording should be verified and calibrated. A protocol with acceptance criteria needs to be established by the suppliers or the irradiator operator.

The operational qualification tests and checks cover all aspects that are critical to the process. They need to demonstrate the capability of the equipment to deliver the range of operating parameters and operating limits set in the equipment specification.

Dose mapping is used to determine the dose distribution pattern and the dose values in irradiation containers filled with homogeneous material, the predictability and the reproducibility. This will in particular aim at verifying:

(a) The DUR that is obtained over a range of densities similar to the range of densities of the products that will be treated routinely;
(b) The exposure time required for a given dose at a given density;
(c) The throughput of the irradiator at various doses and densities.

Dose mappings need to be performed with homogeneous material in a variety of conditions reflecting routine operation conditions such as partly filled containers, widely varying operating conditions (conveyor speed) or loads of various densities in the irradiator.

For accelerators, qualification includes measuring the mean energy of the electron beam, beam spot profile and scan width. The beam energy, which determines the penetration of electrons, is measured by determining the depth–dose distribution along the beam axis in a reference material such as polystyrene or water. For this purpose, several thin film dosimeters located at different depths in the reference material are irradiated.

The uniformity of the doses delivered on the surface of an irradiation unit depends on the beam spot profile and scan width. The scan width is usually measured by placing several dosimeters or strips of dosimeter film along the scan direction. It needs to be ensured that the radiation zone covers the sides of the irradiation unit relative to the conveyor movement. The information generated during operational qualification needs to be reviewed and the outcome of the review recorded.

5.4. PERFORMANCE QUALIFICATION

The objective of performance qualification is to demonstrate that the equipment, as installed and properly operated, consistently performs as expected and that process specifications can be met. Dose mapping is the main tool. The products that are intended for routine processing or products of identical physical characteristics are used for performance qualification. The exercise needs to confirm the appropriate process parameters such as timer setting, product load configuration and conveyor speed.

Before performance qualification starts, a protocol with acceptance criteria should be established by the irradiator operator in liaison with the customer. Since dose distribution will vary with product characteristics, arrangement of the load within the irradiation container and path inside the irradiator, performance qualification needs to be performed for each set of parameters that will be used for routine processing.

The main outcome of performance qualification is a specification for the particular product and load configuration. This specification should be reviewed and approved by both the irradiator and the customer (see Section 7.2).

6. PRODUCT CHARACTERIZATION

6.1. PRODUCT DEFINITION

The product to be irradiated needs to be precisely specified, and quantitative characteristics need to include tolerances. If the individual food items or the package units vary in size and weight, the acceptable range needs to be indicated. This will generally be the case for non-processed agricultural products. The validity of the stated range is to be supported by dose mapping.

6.2. PRODUCT SAFETY AND QUALITY BEFORE IRRADIATION

It is the responsibility of the customer (the party that owns the food) to ensure that their product meets the suitable safety and quality standards. However, while the product is under their custody, irradiation operators have a duty of care if products are in obvious violation of the provisions of the technical agreement (e.g. issues associated with packaging, quality, traceability, temperature or physical aspect of the product).

The irradiation of food is justified only when it fulfils a technological requirement or is beneficial for the protection of consumer health. Irradiation cannot be used as a substitute to good agricultural practices, hygienic practices and good manufacturing practices or to correct quality deficiencies. Undue contamination with microorganisms and insects prior to irradiation is not acceptable, and where contamination appears unavoidable, all possible measures should be taken to keep it minimal.

6.2.1. Sanitary applications

All food products should be prepared, processed and transported hygienically in accordance with the provisions of the Codex Alimentarius General Principles of Food Hygiene [4] as well as the Codex Alimentarius codes of hygienic practice developed for specific products. This principle applies to, for example:

(a) Products of animal origin such as raw, fresh, frozen, cooked and processed meats, products of plant origin, such as tofu or sprouts, and ready-to-eat meals irradiated to eliminate pathogens or to extend shelf life.
(b) Dried fruit irradiated for insect control: The presence of insect should be minimal, and the moisture content less than 10–12% for dried nuts and less than 20–35% for other dried fruit.
(c) Dried fish irradiated for insect control: The moisture content should be less than 15%. For salted dried fish, the salt content should be between 4% and 15%.
(d) Spices, herbs and dehydrated vegetable seasonings irradiated for microbial decontamination. The number of coliforms and melds should be less than 10^4 and 10^5 CFU/g (colony forming unit per gram), respectively.

For some of these products, specific recommendations regarding various classes of products were published by the International Consultative Group on Food Irradiation in a series of publications entitled Code of Good Irradiation

Practice.[3] In these codes, the approach to ensure that only hygienically handled food will be irradiated is based on the three-class sampling plan introduced by the International Commission on Microbiological Specifications for Foods in 1986.

The three class plans include four values on which the acceptability of lots to be irradiated is based:

— *N* is the number of samples units to be examined;
— *C* is the maximum number of sample units with values between *m* and *M* for the lot to be acceptable;
— *m* is the value of the aerobic plate count (APC) at or below which no concern is recognized;
— *M* is the APC value above which the lot is rejected.

Table 5 provides the values for *N*, *C*, *m* and *M* for different foods.

TABLE 5. VALUES OF *N*, *C*, *m* AND *M* FOR VARIOUS PRODUCTS

Product	Microbiological test	*N*	*C*	*m*	*M*
Red meat (beef, lamb and pork)					
Carcass meat before chilling	APC (35°C or 37°C)	5	3	10^5	10^6
Chilled carcasses	APC (20°C or 25°C)	5	3	10^6	10^7
Carcass meat (frozen)	APC (20°C or 25°C)	5	3	10^5	10^7
Poultry	APC (20°C)	5	3	5×10^5	10^7
Fish and crustacean	APC (20°C)	5	3	5×10^5	10^7
Cooked, peeled frozen shrimps and prawns	APC (30°C)	5	2	10^5	10^6
	Staphylococcus aureus	5	2	5×10^2	5×10^3
	Salmonella	5	0	0	n.a.[a]

Note: APC — aerobic plate count.
[a] n.a.: not applicable.

[3] See http://www-naweb.iaea.org/nafa/fep/public/manuals-fep.html for further information.

It is not necessary to establish specific criteria for food that has been irradiated. Indeed, irradiated products need to meet the same requirements, including microbiological requirements, as similar food which is marketed unprocessed or processed by another method.

6.2.2. Phytosanitary applications

The International Standards for Phytosanitary Measures (ISPM), published by the Food and Agricultural Organization of the United Nations, contain requirements to ensure that the product or commodity is suitable for an effective irradiation treatment, in particular: ISPM No. 7, Phytosanitary Certification System [20]; and ISPM No. 18, Guidelines for the Use of Irradiation as a Phytosanitary Measure [21].

6.2.3. Other applications

When bulbs and tubers are irradiated for sprouting inhibition, only varieties of proven storage quality are suitable for irradiation and long term storage. Bulbs and tubers should be at the proper stage of harvesting maturation, free from damage and healthy. Potatoes damaged during harvesting and handling should be allowed to heal before irradiation. Similarly, damaged onions and garlic should be properly cured.

6.3. PRODUCT SPECIFICATION

Typically, the product specification will include the following characteristics:

(a) Product name, description and means of identifying it:
- — Product;
- — Botanical name;
- — Variety;
- — Place of origin;
- — Lot number;
- — Packing date;
- — Packing house;
- — Quantity;
- — Net weight.

(b) Package materials:
   — Weight;
   — Shape;
   — Dimensions;
   — Configuration.
   — For electron beam irradiation, the orientation of the product should be specified, since it is often critical;
   — Packaging components such as pallet, wrap film, corner protectors and straps should also be described.
(c) Pre-irradiation and post-irradiation storage conditions and particular precautions that should be taken.
(d) Quality of the product before irradiation.
(e) Purpose of the irradiation treatment, for example sprouting inhibition, phytosanitary, pathogenic control or shelf life extension.

6.4. PACKAGING AND LABELLING

6.4.1. Packaging

One of the main functions of packaging is to protect products from reinfestation or recontamination, hence the importance of maintaining package integrity. Whenever the purpose of irradiation is to kill insects or microorganisms, products should be packaged before irradiation.

No packaging material that will either undergo significant alteration of its functional properties or yield toxic substances which can be transferred by contact to the foods may be used. The lower the dose, the less likely this is to happen. Generally, the packaging that is used for similar products that are not irradiated can be used. The size and shape of containers or packages may have to be adapted to the characteristics of the irradiation facility such as penetration of the radiation and size or maximum load of irradiation containers.

In some applications, vacuum packaging may be desirable to avoid rancidity. The atmosphere inside the package is influenced by the permeability of the packaging material to various gases. Modified atmospheres can be used in conjunction with irradiation to preserve sensory qualities and extend shelf life in products such as meat, prepared salads or ready-to-eat meals. Attention should be paid to the fact that the gaseous composition inside the package may have an effect on the sensitivity of the target organisms to irradiation. For further information, see ASTM F1640-03, Standard Guide for Packaging Materials for Food to Be Irradiated [22], and 21 CFR 179.45, Packaging Materials for Use during the Irradiation of Prepackaged Foods [23].

Foods and their packaging materials need to be of suitable quality, in an acceptable hygienic condition and in any other regard appropriate for irradiation [4]. Food and packaging materials should be handled, before and after irradiation, according to good manufacturing practices taking into account the particular requirements of the processing technology.

For phytosanitary treatments, the articles should be contained in insect proof packaging (e.g. insect proof cartons) which has no openings that will allow the entry of regulated pests. If openings are necessary for ventilation, they should be covered with mesh of a suitable size that will not allow pests to enter. The cartons may be constructed of any material that prevents the entry of pests and prevents oviposition (laying eggs) into the articles in the carton.

If phytosanitary treatments are not conducted in insect proof packaging, treated lots should be wrapped before leaving the irradiation facility in one of the following ways:

— With shrink wrap;
— With net wrapping;
— With strapping so that each carton on an outside row of the pallet load is constrained by a metal or plastic strap.

The requirement for post-treatment wrapping (to ensure phytosanitary security) may be waived if the cartons are pest proof and the pallet load is to be broken down into smaller shipping units, such as cargo containers. In such cases, the treated articles may need to be held in secured holding rooms/areas until loaded for shipment. Treated articles are not to be mixed with untreated or improperly treated produce. The holding rooms/areas should be secured at all times to prevent contamination of treated articles with untreated articles and entry of unauthorized personnel.

All shipments using wood packing material should comply with ISPM No. 15, Regulation of Wood Packaging Material in International Trade [24].

6.4.2. Labelling

The Codex General Standard for the Labelling of Prepackaged Foods [25] requires the label of a food which has been treated with ionizing radiation to carry a written statement indicating that treatment in close proximity to the name of the food. When the Radura logo is used (see Fig. 19) — the international food irradiation symbol created in the Netherlands in the late 1960s — it should be in close proximity to the name of the food. The Codex Standard [25] also states that

FIG. 19. The Radura logo.

a food containing more than 5% of any one ingredient that has been irradiated should be so declared in the list of ingredients. When a single ingredient product is prepared from a raw material which has been irradiated, the label of the product needs to contain a statement indicating the treatment.

Labelling needs to meet all requirements established by relevant authorities in the country in which the product is marketed. How to state that the product was irradiated varies from one country to another, but all regulations require that consumer know that the product was irradiated. It should also be made clear on the relevant shipping documents. In English, expressions such as 'irradiated' or 'treated with ionizing radiation' are usually required on prepackaged irradiated foods. For products sold in bulk to the end consumer, the international logo and the words 'irradiated' or 'treated with ionizing radiation' should appear together with the name of the product on the container in which products are placed. The option often exists to accompany these words with the Radura logo (see Fig. 19).

In addition to the mandatory statements, complementary information may be given to indicate the benefits of irradiation such as:

— Protecting the environment;
— Improving safety;
— Maintaining quality;
— Meeting quarantine requirements.

7. PROCESS CHARACTERIZATION

7.1. PROCESS DEFINITION

Defining an irradiation process is essentially setting two limits: minimum and maximum dose levels for the treatment. Thus, the acceptable dose range is defined by the interval between the two dose levels. Where regulatory limits exist for a given product or application, they prevail. Consequently, the defined process should meet regulatory limits. Regulatory limits generally set a maximum dose, but for phytosanitary applications they also set a minimum dose.

When defining the process, the minimum dose level is the dose at and above which a defined technical purpose is achieved, and the maximum dose level is the dose beyond which quality is impaired in some way (e.g. structural integrity, functional properties or sensory attributes are adversely affected, or wholesomeness or consumer safety are compromised) (see Fig. 20).

There are cases where, for process optimization, it may be acceptable that the benefit is not fully obtained or some detriment is acceptable (see Fig. 21). An example of such a compromise is when the dose used to decontaminate a purified enzyme is kept low in order to preserve its activity.

The values of the limits will depend on many factors:

(a) The type of product;
(b) The sensitivity to irradiation in terms of sensory quality or functional properties;
(c) The type and number of organisms contaminating the product;
(d) The desired final result (e.g. time after which insects will die, population of microorganism and extension of shelf life);
(e) The variety and harvesting stage for plant products;
(f) The packaging atmosphere;
(g) The time elapsed before irradiation;
(h) The temperature during irradiation.

These limits can be experimentally determined with samples of products. The conditions in which samples are prepared and treated should be as close as possible to practical conditions.

For phytosanitary applications, minimal doses have been internationally accepted to control pests in international trade. They can be found in the annexes of ISPM No. 28, Phytosanitary Treatments for Regulated Pests [26].

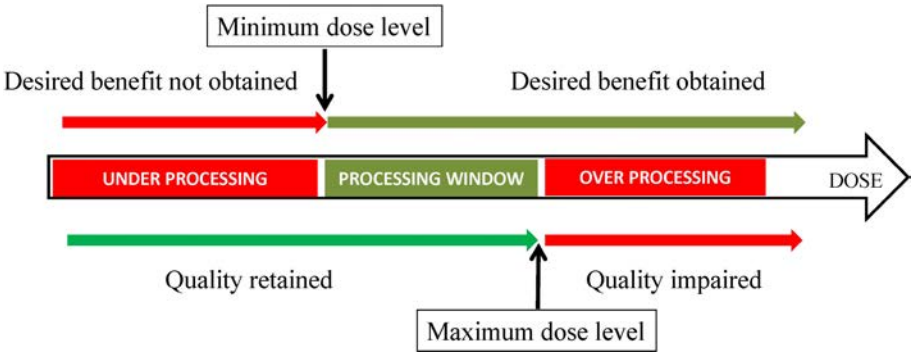


FIG. 20. Rationale for minimum and maximum dose levels.

The Codex Alimentarius General Standard for Irradiated Foods [5] states that: "The maximum absorbed dose delivered to a food should not exceed 10 kGy, except when necessary to achieve a legitimate technological purpose."

Pre- and post-irradiation storage and environmental conditions also need to be defined. They should maintain the integrity of products throughout the process. All measures should be taken to prevent contamination by insects or microorganisms. It is generally desirable that the pre-irradiation storage period be short.

For fresh and frozen products, the cold chain is to be maintained, including during irradiation. Typically, the temperature is not to exceed 4°C without freezing for fresh meats and poultry and 3°C for fresh fish and seafood. The temperature of frozen products is not to rise above −18°C.

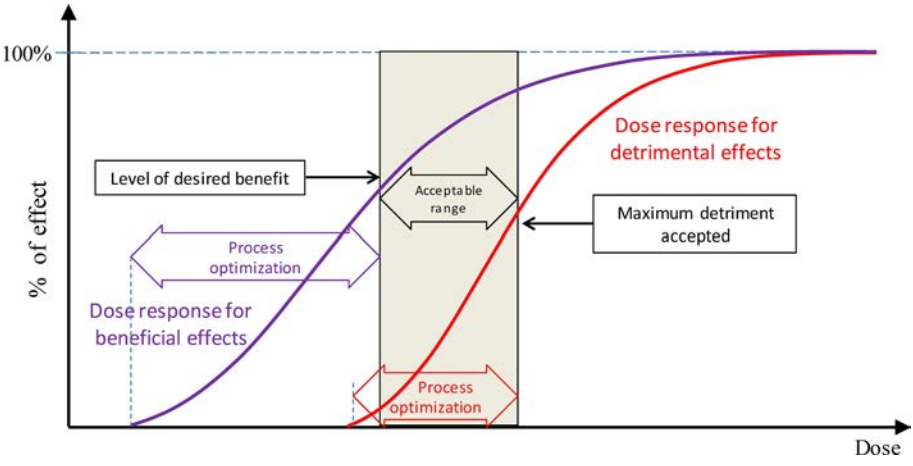


FIG. 21. Process optimization and dose range specification.

7.2. PROCESS SPECIFICATION

The customer is responsible for specifying the dose range to the irradiator operator. It is the responsibility of the irradiator operator to irradiate within the specified dose range. However, the irradiator operator is not responsible for achieving a particular technological purpose.

During performance qualification, the operator will verify that it is possible to deliver doses within this range when irradiating the commercial loads. Uncertainties will be taken into account, and will lead to a target dose range that will not be as wide as the initially specified dose range (see Fig. 22).

Following the performance qualification, a process specification is to be established and approved by the customer and the irradiation operator for each product, including:

— A description of the packaged product, including weight, dimensions, density and orientation of product within the package and acceptable variations (see Section 6.1);
— The labelling requirements (wording and logo);
— Required minimum and maximum absorbed dose;
— A reference to the performance (re)qualification dose mapping;
— The configuration of the load in the irradiation container and the way in which it is presented to the irradiation source;
— The irradiator operating conditions and limits (i.e. beam characteristics and conveyor speed);

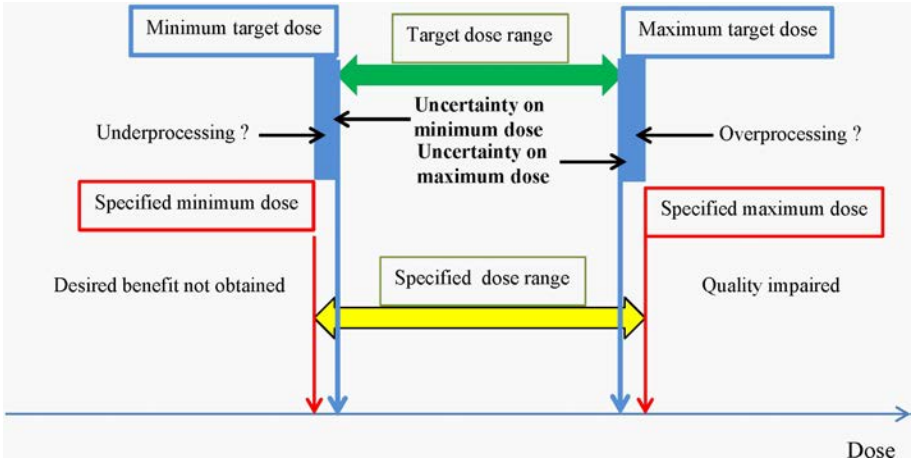


FIG. 22. Specified dose range and target dose range.

— The conveyor path(s) to be used in multi-pass irradiators (gamma only);
— The specified and the target dose range;
— The routine reference dosimeter type and position(s);
— The relationship between the reference dose and the minimum and the maximum dose;
— The number and frequency of routine dosimeters per consignment;
— The products that can be simultaneously present in the irradiation chamber (for gamma irradiators);
— Requirements between exposures for product requiring multiple exposures (e.g. re-orientation or time restrictions);
— Special handling and storage conditions required such as temperature conditions, storage in a close holding room and segregation from undesirable aromas.

The irradiator operator and the customer should establish a written technical agreement. Besides the process specification, the agreement should detail the respective responsibilities. The customer is responsible for delivering the food according to the product specification. The irradiator operator is responsible for processing the products according to the process specification.

For phytosanitary treatments, responsibilities will generally be defined by the relevant competent authorities and by reference to relevant standards such as ISPM No. 18 [21] and ISPM No. 28 [26].

8. QUALITY MANAGEMENT

8.1. QUALITY MANAGEMENT SYSTEMS

A food irradiation facility should be managed in accordance with defined quality management systems, comply with good hygiene practices and recognize the relevant regulatory authority requirements.

8.1.1. Food hygiene

The Codex Alimentarius Code of Practice for Radiation Processing of Food [27] recommends that primary food products intended for radiation processing should comply with the Codex Alimentarius General Principles of Food Hygiene [4]. These should be supplemented by the Codex Alimentarius Codex codes of hygienic practice developed for specific products (e.g. Code of

Hygienic Practice for Fresh Fruits and Vegetables [28]). These specific Codex codes of practice follow the food chain from primary production through to final consumption, highlighting the key hygiene controls at each stage, and recommend a Hazard Analysis and Critical Control Point (HACCP) based approach as described in the annex of Ref. [4]. The Codex Alimentarius Code of Practice for Radiation Processing of Food [27] also recommends that reference be made to other relevant Codex standards and codes of practice for primary production and harvesting, which ensure that food is safe and suitable for human consumption. However, in irradiation facilities where only packaged products are handled, some of the sanitary practices and requirements of the food industry, such as washable surfaces, sanitation of equipment or protective cloth for personnel, may not be relevant.

8.1.2. Hazard Analysis and Critical Control Point

Described in the Codex Alimentarius General Principles of Food Hygiene [4], HACCP has replaced the traditional approach of inspection and microbiological testing by a systematic approach to hazard assessment and a focus on factors specifically affecting food safety. The HACCP method is based on seven principles [4]:

(1) Conduct a hazard analysis, the purpose of which is to develop a list of hazards which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. A hazard is a biological, chemical or physical agent that may cause an unacceptable consumer health risk.
(2) Identify critical control points, which are the points in a specific food system at which a loss of control may result in an unacceptable health risk.
(3) Establish critical limits.
(4) Establish monitoring for each critical control point.
(5) Establish corrective actions when critical limit deviations occur.
(6) Establish procedures to verify that the HACCP system is effective.
(7) Establish documentation concerning all procedures and records appropriate to these principles and their application.

The Codex Alimentarius General Standard for Irradiated Foods recommends that food materials be prepared, processed and transported in accordance with the seven principles of HACCP where relevant for safety purposes. Article 5 of Regulation (EC) 852/2004 [29] also requires that: “Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.” In early 2013, the United States Food and Drug

Administration published two proposed rules containing provisions requiring hazard analysis and risk based preventive controls:

(a) Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.
(b) Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.

8.1.3. ISO standards

Since the early 1990s, ISO 9001 has become a universal reference for quality systems. The standard specifies the requirements for a quality management system where an organization needs to demonstrate its ability to consistently provide products or services that meet all applicable requirements and wants to enhance customer satisfaction. A large number of irradiation companies have now implemented a quality system complying with ISO 9001:2008 [1].

ISO 9001:2008 [1] specifies that the organization is to issue and maintain the following six documented procedures:

(a) Control of Documents (clause 4.2.3);
(b) Control of Records (clause 4.2.4);
(c) Internal Audits (clause 8.2.2);
(d) Control of Nonconforming Product/Service (clause 8.3);
(e) Corrective Action (clause 8.5.2);
(f) Preventive Action (clause 8.5.3).

In addition to these procedures, ISO 9001:2008 [1] requires the organization to document any other procedures required for its effective operation. The standard also requires the organization to issue and communicate a documented quality policy, a quality plan and numerous records, as specified throughout the standard.

ISO 22000:2005, Food Safety Management Systems: Requirements for any Organisation in the Food Chain [30], specifies the requirements for a food safety management system where an organization in the food chain needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption. The standard incorporates pre-requisite programmes, which provide basic environmental and operating conditions necessary for the production of safe and wholesome food, as well as the Codex HACCP principles.

In 2011, ISO 14470:2011 [3] was published — the first standard to contain requirements for the development, validation and routine control of food irradiation. This standard was developed on the basis of the experience gained with the ISO standards addressing sterilization of medical devices, such as ISO 11137-3:2006 for radiation sterilization [31].

8.2. DOCUMENTATION

Good documentation practices — which are the rules to properly establish, maintain and archive documents — are seldom explicitly required by regulatory agencies because they have become an expected practice. The general expectations include:

(a) Documents are concise, accurate, legible and traceable.
(b) Documents are approved, reviewed, signed and dated by designated personnel. Changes and updates also go through the review and approval process. If a mistake has been made, it is corrected by drawing a single line through the error, making the correction next to the error, signing and dating the correction, and writing an explanation for the error.
(c) Provisions are in place to ensure that only current documents (procedures, work instructions, forms and labels) are in use.
(d) Documents are available at the point of use, for example loading patterns at the loading station of the irradiator or dosimeter reading procedure where dosimeters are read.
(e) Records established to provide evidence of conformity to requirements, whether on paper or in electronic form, clearly show the data, when they were recorded, and the name and signature of the person who recorded them.
(f) Provisions are in place to ensure the identification, storage, conservation, protection, retrieval, retention and disposition of records.

A standard operating procedure (SOP) is a detailed document that specifically defines how an individual job function is to be performed. It describes the job position assigned to perform the task, the equipment and supplies needed to complete the task, and the documentation required to complete the task. Its contents include:

— Number (for reference purposes);
— Title;
— Date of issue or revision, and a history of the changes made;

— Scope of field of application;
— Purpose of the SOP;
— Operations;
— Documentation;
— Names and signatures of those who reviewed and approved it.

In order to demonstrate conformity to the requirements, records provide key evidence that activities have been performed or results have been achieved. Table 6 provides a non-exhaustive list of records normally found in an irradiation facility.

TABLE 6. LIST OF CONTENTS

Item	Contents
Records used by the operator	List of procedures, forms and labels
	List of records
	Characterization of the irradiator, the radiation source and the equipment
	Installation qualification and operational qualification plan, protocols and reports
	Dosimeters and instruments calibration records
	Specifications, purchase orders and incoming control of critical supplies
	List of instruments requiring calibration, calibration schedule and records
	List of instruments not requiring calibration
	Schedule and reports of internal audits, external audits and management reviews
	Job descriptions and training records of personnel
	Maintenance schedule and reports
	List of corrections, corrective and preventive actions
Records for a particular customer	Performance qualification protocol and report including dose mapping reports
	Process specification
	Technical agreement

TABLE 6. LIST OF CONTENTS (cont.)

Item	Contents
Records for each lot	Lot form with a unique lot number, identifying the customer, the product, and stating the quantities and the specification to be used
	Delivery and shipping documents
	Process control data
	Routine dosimetry report
	Non-conformance report
	Product release form
	Certificates

8.3. PERSONNEL

Personnel play a key role in the capability of the irradiation operator to conduct irradiation treatments. The management is responsible for hiring personnel having appropriate education and experience for the position that they will fill. They need to hold appropriate qualifications and credentials reflecting government requirements of the country in which the facility is located. Where food is handled, all employees should have at least a basic knowledge of food hygiene and good hygienic practices as recommended in the sections VII and X of the Codex Alimentarius General Principles of Food Hygiene [4].

The Codex Alimentarius General Standard for Irradiated Foods [5] makes recommendations regarding the need for adequate, trained and competent personnel. The management should ensure that the employees are aware of the relevance and importance of their activities. In each employee's file, there should be an updated job description and list of critical tasks for which the employee is authorized. There should be a list of requirements to be met before an employee is formally authorized to perform critical tasks such as:

(a) Setting routine process parameters;
(b) Calibrating dosimeters;
(c) Reading dosimeters;
(d) Calibrating measuring instruments;
(e) Analysing dosimetry reports;
(f) Releasing lots;
(g) Approving procedures;

(h) Establishing and approving processing specification or technical agreements;
(i) Performing critical maintenance tasks on an electron accelerator or X ray machine;
(j) Rearranging source elements on a source rack.

The training needs of the employees should be identified. To fulfil these needs, there should be a plan in order to provide new or updated knowledge and skills. The training sessions should be documented, and each participating employee's training records should be regularly updated (see Fig. 23). At the end of each training session, it is important to assess the effectiveness of the session, for example by giving a written test or a practical exercise that will be assessed or graded.

Employee Record			
Name			
Contact details			
In case of emergency contact			
Education			
Training history			
Previous experience			
Job title			
Job description			
Authorizations		Y/N	Since
Calibrate instruments		*N*	-
Calibrate dosimeters		*N*	-
Calculate and set process parameters		*Y*	*Date*
Schedule the production sequence		*Y*	*Date*
Read dosimeters		*N*	-
Analyze dose mapping reports		*Y*	*Date*
Release products		*N*	-
Review and sign certificates		*Y*	*Date*
….			
Training history			
Date		Course title	Assessment
Date		*Induction course*	
Date		*Dosimetry*	
Date		*Principles of Food Hygiene*	

FIG. 23. Example of an employee record.

8.4. HOUSEKEEPING

8.4.1. Cleanliness

Food processors make great efforts to produce food in sanitary conditions and offer a good presentation of the packages. Irradiation is expected to bring the quality standard to an even higher level. This is why irradiation operators need to take particular care in keeping their facilities clean and tidy and in preserving the integrity of the products under their custody. The management needs to provide the appropriate resources in equipment, personnel and consumables.

The cleaning tasks, the areas concerned, the frequencies and the responsibilities need to be defined in writing. Schedules and records need to be kept. Before and after irradiation, products should not rest on the floor (i.e. placed on a pallet free from infestation). Sufficient space should be left between the products and the walls to allow cleaning. Damaged packages should be isolated, discarded or repaired in order to keep the barrier against infestation or contamination. Spilled product should be immediately removed and disposed in order to avoid attracting pests. Trash bins should be available in sufficient numbers, large enough and regularly emptied.

8.4.2. Pest control

Pest control may be outsourced to a reputable contractor. If so, then a technical agreement should be in place. The pest control plan and schedule need to be defined and the places of the baits and control equipment marked on a facility plan. When chemical, physical or biological treatments are used, the treatment should be carried out without posing threat to the safety or suitability of food. Records of intervention should be filed.

8.4.2.1. Rodents

The location of bait is to be marked on a wall or on the floor. If there are signs that rodents may be present, intervention is required before the next periodical treatment.

8.4.2.2. Insects

The warehouses should be equipped with sufficient insectocutors, which should be permanently turned on. In case of infestation, prompt curative treatment is required. If the warehouse needs to be fumigated, potential consequences on stored products need to be assessed.

It is good practice to keep doors closed whenever possible to prevent insects from entering the warehouse. This is especially critical where irradiation is used as a phytosanitary measure and reinforced prevention measures are required (see Section 3.1).

8.4.2.3. Birds

Birds may become a serious nuisance in the warehouse of irradiation facilities. Keeping the warehouse doors closed as much as possible is a good preventative measure. The building design should avoid the creation of 'bird parlours', but it is also possible to place nets in order to put some spaces off limits to birds. Noise emission systems supposed to keep birds away are not always effective. If birds are present, nests should be found and destroyed.

9. ROUTINE MONITORING AND CONTROL

9.1. PROCESS CONTROL

Treatment of goods may take place only if the facility is in good working order. This means that:

(a) The equipment works properly and all scheduled maintenance tasks have been performed.
(b) Periodic tests have been performed.
(c) Measuring instruments and dosimeters are calibrated.
(d) Scheduled requalification has been performed.
(e) All necessary procedures and appropriate methods are in place for monitoring, measurement and analysis of the process.

9.1.1. Receiving products

The organization sending products to the irradiator operator needs to ensure that they are of a nature and quality that make them suitable for the irradiation treatment that is envisaged (see Section 6.2).

The irradiator operator needs to log incoming products and to give them a unique irradiation lot number. A precise definition of an irradiation lot number should be documented. The use of this irradiation lot number at each step through

the irradiation facility ensures internal traceability and should appear on all records generated by the irradiator operator for easy reconciliation.

Logging and labelling of products should take place as soon as products are received. Systems for quantifying product and maintaining product inventory need to be implemented throughout product receiving, loading, unloading, handling and release. There needs to be procedures to handle products and maintain their integrity before, during and after irradiation. While they may help to assist in production inventory control, radiation sensitive indicators that change colour when irradiated (also known as 'go-no go') are not to be used to replace other administrative inventory control procedures or as a proof of satisfactory radiation processing. The colour is not always stable and may be affected by light, heat or certain chemicals.

Any discrepancy in the inventory or damage to product should be resolved before processing or release.

9.1.2. Preparation of products for processing

In the process load, dosimeters need to be placed at the predetermined maximum and minimum dose positions or at a qualified reference dose location with the required frequency. This information should be readily available to the person performing the task.

In continuous gamma irradiators, the frequency of dosimeters should be such that there is always at least one dosimeter inside the irradiation chamber. In addition, a dosimeter should be placed on the first and last irradiation container of a production run. In an electron beam facility, there should always be one dosimeter at the start of a production run. For long runs, dosimeters should also — as a minimum — be placed near the middle of the run, at the end of the run and at other intervals as appropriate.

Products should be loaded in the product loading configuration according to the process specification. The loading configuration of each product needs to be readily available to the person performing the task. Provisions should be in place to ensure that the operator loads the right products in the irradiation container (i.e. the products that were scheduled). Only authorized personnel may set the process parameters (e.g. irradiation time or conveyor speed).

9.1.3. Post-processing controls

Products should be placed in the appropriate zone of the treated products area. The processing records, the count and the condition of the products should be checked, and any issue should be resolved before they are released.

Dosimeters should be retrieved and stored properly before reading. The count of dosimeters should be checked. Dosimeter readings should preferably be generated electronically, using validated software. The software needs to be secure to prevent unauthorized access and tampering of results. Where dosimeter results are routinely printed, the print out should be signed and dated by the reader. If results are not printed, an audit trail needs to be available within the software to provide traceability to the reader and date of reading.

There should be a procedure in place to address cases in which the process specifications have not been met. The customer or regulatory authorities need to be informed as agreed in the technical agreement or the licence. All out of specification results should be recorded in a non-conformance report, which should also contain an analysis to identify the root cause and the decisions on corrections and corrective actions. If a re-read of dosimeters is performed as part of the investigation, and this re-read value is used to release a product, a mechanism should be in place to ensure the validity of this re-read result.

When dosimetry results show that the specified minimum dose was not reached, it may be possible to complement the treatment if there is no risk of exceeding the maximum dose. However, doses may not always be cumulative (see Section 9.2). When the required complement is low, this may prove very difficult, or even impossible, to do in electron beam facilities or large commercial gamma irradiators.

Dosimetry results may also show that the specified maximum dose has been exceeded. In this case, products which have received a dose exceeding the maximum regulatory limit need to be considered as adulterated and properly discarded. Under certain conditions, a concession may be made for those products that received less than the maximum regulatory limit but more than the specified maximum dose if tests demonstrate that their quality and safety are not compromised.

9.2. PROCESS INTERRUPTIONS

Process interruptions are unscheduled and should be distinguished from the normal exposure interruptions common in incremental dose gamma irradiators or in electron beam facilities when products are irradiated on two sides. When a process interruption occurs, the date, time, duration, cause and action taken should be recorded.

The potential impact of the interruption on the efficacy of the total dose should be assessed, since the status of the product infestation or contamination at the end of the first fraction may no longer be the same at the beginning of the second fraction.

In products that do not support microbial growth, doses applied in two fractions separated by several days are cumulative, and if the required minimum dose was not reached, a complement can be applied later. In products that may support microbial growth or may allow insect reproduction or sensitivity and under conditions that may allow an evolution of the phytosanitary or sanitary status, doses applied in fractions may not be cumulative from the point of view of the effect to be achieved.

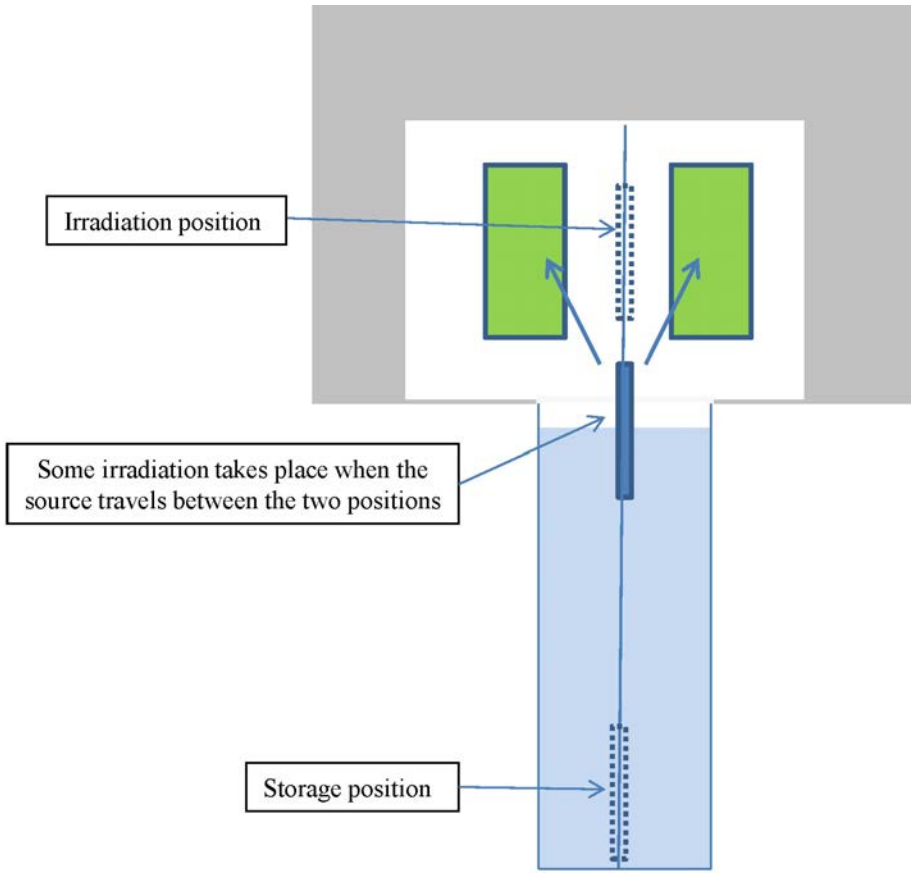


FIG. 24. Irradiation during source transit.

9.3. TRANSIT TIME

In gamma irradiators, it takes a certain amount of time for the source to travel between the irradiation position and the safe storage position. Processing time is counted only when the source is in full operating position. However, products are irradiated for some time that is not accounted for just before the source reaches the operating position or just after it leaves this position, contributing to some extra dose called the transit dose, as illustrated in Fig. 24. With a stationary radiation source, the product also absorbs irradiation during its movement into and out of the radiation field.

The significance of this extra exposure time, called transit time, needs to be assessed. It is especially critical for low doses such as those used for phytosanitary applications.

9.4. INFLUENCE OF OTHER PRODUCTS IN THE GAMMA IRRADIATOR

Generally, a homogeneous radiation treatment is only achieved when the irradiation chamber is completely filled with the product to be treated. Thus, at the beginning and at the end of an irradiation run, when the irradiation chamber is not completely filled, the first and last irradiation containers especially accumulate higher doses during their passage, as they are not shielded from the source by other irradiation containers during a significant portion of their pass. In batch operation and incremental dose facilities, similar problems may be experienced if products with very different bulk densities are irradiated at the same time.

This can be mitigated by the use of process loads with ‘dummy’ products at both the ends of a production run if the dose distribution is found to be unacceptable. Dummy products may be made of scrap or rejects or low value products, such as grain, legumes, water, rejected fruit and saw dust. They need to be packed in such a way that their overall density is close to that of the processed product.

It is also useful to sort products into processing categories, which are groups of products that can be irradiated together by sorting them according to several ranges of bulk densities. This is irrelevant for electron beam processing where a single package at a time is irradiated and where it is even possible to give consecutive packages different radiation treatments, although this is generally not done.

9.5. RE-IRRADIATION

Irradiated food is not to be re-irradiated. According to the Codex Alimentarius General Standard for Irradiated Foods [5], food is not considered as having been re-irradiated when:

(a) The irradiated food is prepared from materials which have been irradiated at low dose levels for purposes other than food safety (e.g. quarantine control, and prevention of the sprouting of roots and tubers);
(b) The total food already containing less than 5% of irradiated ingredient is irradiated;
(c) The full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one increment as part of processing for a specific technological purpose.

The cumulative maximum absorbed dose delivered should not exceed 10 kGy as a result of re-irradiation except when it is necessary to achieve a legitimate technological purpose and should not compromise the safety or wholesomeness of the food [5].

Commodities treated for phytosanitary purpose or food with low moisture content (cereals, pulses, dehydrated foods and other such commodities) irradiated for the purpose of controlling insect re-infestation may be re-irradiated for sanitary purposes [5].

9.6. PRODUCT RELEASE FROM IRRADIATION

Procedures for product release following irradiation treatment should be specified. Typical release conditions include:

(a) Products were treated in compliance with the specification.
(b) All records are available, reviewed and signed.
(c) Any damage, non-conformance or deviation issue was resolved and documented.
(d) The count of product is correct.
(e) The process was applied in compliance with all applicable procedures.

Release needs to be a formal process that is the object of a specific record signed by authorized personnel. The irradiator operator needs to ensure that products considered as non-conforming are identified and controlled to prevent their unintended use or release.

9.7. RECORDS

All records should be available on request to competent authorities, the customer and other parties having a legitimate need for access to the information. The Codex Alimentarius Code of Practice for Radiation Processing of Food [27] requires that an adequate system should be in place so that specific consignments of food products can be traced back to the irradiation facility and the source from which they were received for processing.

Evidence for correct processing depends on the maintenance of full and accurate records. Records relevant to irradiation treatments performed need to be maintained for a specified time period, which should not be less than that specified in the current legislation. For phytosanitary treatments, ISPM No. 18 [21] specifies a minimum period of one year.

Records should include at least the following:

— Import/export permit number (if applicable);
— Name and address of facility;
— Name and address of product owner;
— Description of product;
— Country of origin;
— Treatment details (e.g. treatment date, dose rate, exposure time, minimum dose, maximum dose, dosimetry system and purpose);
— Correction in case of non-conformance.

9.8. CERTIFICATES

Treatment certificates should accompany goods treated by the approved provider. All details should be legible and free from erasures and non-certified alterations. The certificate should be on the organization letterhead, signed, dated and contain the following details:

— Description of goods;
— Quantity declared;
— Purpose of treatment;
— Radiation source;
— Date of treatment;
— Place of treatment;
— Identification of treatment facility;
— Minimum and maximum absorbed dose (specified and in some cases actual);

— Lot number;
— Consignment owner;
— Any observed deviation from the treatment specification.

The treatment certificate should be attached to the phytosanitary certificate, which should comply with section 8.2 of ISPM No. 18 [21].

10. MAINTAINING PROCESS EFFECTIVENESS

The irradiation facility is not to be used if the scheduled tasks have not been performed. These tasks include periodic tests, calibrations, maintenance tasks and necessary requalification, of which the outcomes are to be recorded. Failing to perform these tasks in a timely manner may result in the facility being unsafe, not properly functioning or yielding unreliable results.

10.1. CALIBRATION AND RECALIBRATION

Procedures need to be in place and updated as necessary for implementing and documenting calibration measurement and control systems. All systems are to be periodically checked to ensure that they are functioning according to their specifications. The calibrations need to be traceable to national or international standards. Instrumentation used to control, indicate or record the irradiation process should be recalibrated at the predetermined frequency. Figure 25 provides examples of records for calibrated instruments. Instruments that are modified or serviced need to be recalibrated before being used again.

10.2. MAINTENANCE OF EQUIPMENT

Maintenance procedures cover all parts or sub-assemblies of equipment that require maintenance and state how often maintenance tasks should be performed. Working instructions detail how the maintenance task is be carried out. Preventive maintenance and predictive maintenance are to be encouraged.

Inventory of calibrated instruments				
Name	Code name	Location	Operating work instruction	Calibration procedure
Spectrophotometer	*SPECTRO*	*Dosimetry Lab*	*Supplier manual*	*CALPRO 07*
Stopwatch	*STOP*	*Dosimetry Lab*	*Supplier manual*	*CALPRO 06*
Main Timer	*TIME1*	*Control room*	*Supplier manual*	*CALPRO 01*
Temperature data logger	*TEMPLOG*	*Dosimetry Lab*	*WI 26*	*CALPRO 11*

Calibrated instrument individual record	
Name	*Spectrophotometer*
Code name	*SPECTRO1*
Brand	*ABC*
Model	*XBZ*
Serial number	*123456*
Supplier	
In use since	*dd/mm/yy*
Service Records	
Date: Problem: Action: Recalibrated on: Back in service: Status:	

Calibration schedule					
Instrument	Calibration	Frequency	Last calibration	Next calibration	
				Between	And
X	Internal:	3 months	15/03/12	05/06/12	15/06/12
Y	External: By	1 year	25/11/11	25/10/12	25/11/12

FIG. 25. Examples of records for calibrated instruments.

The maintenance schedule is best presented in the form of a calendar clearly indicating the deadline for each maintenance task. Some of the maintenance tasks are critical and should be performed only by qualified personnel with the predetermined skills and knowledge or with the specific training. A formal authorization system should be in place. Maintenance procedures and records need to be reviewed at specified intervals by a designated person and the results of the review need to be documented.

10.3. REQUALIFICATION OF THE PROCESS

A schedule, rules and a protocol with clear acceptance criteria for periodic operational and performance requalification procedures need to be in place. One year is generally accepted as the maximum interval before requalification. The extent of the requalification may take into account the history of the facility and

the routine treatments over the past months. Requalification needs to be carried out in a timely manner.

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

10.4. ASSESSMENT OF CHANGE

The potential impact on process specifications should be reported by the relevant party and assessed before the change is made. Changes in the specified product (size, weight, quantity and distribution within the package), its packaging (material, size and weight) or the way it is presented for irradiation (configuration in the irradiation container, and path within the irradiator) may have an effect on dose values and distribution. It is also the case with engineering changes such as addition, removal or rearrangement of source elements and modification of the source pass mechanism in gamma irradiators, modification of the conveyor under the scanning horn or change of parts that may affect the characteristics of the radiation field for electron beams or X rays.

After the change, a new dose mapping is required in order to assess the appropriateness of the irradiation process to meet the existing specifications. In instances where the specification is no longer met, the product configuration or the engineering changes may have to be adjusted. If the specification is still not met, the specification will have to be revised in agreement with the customer and or with the authorities. The outcome of the assessment, including the rationale for decisions reached, is to be recorded.

11. AUDITS

Irradiation facilities operate in a highly regulated environment and are frequently audited, sometimes more than once a month. Relevant regulatory authorities including national plant protection organizations will conduct site assessments (audits) in order to establish that the irradiator operator is capable of performing irradiation treatments to the required specifications.

Auditors should be knowledgeable in the domain that they audit. This is required to achieve a good understanding of the whole system, identify potential

loopholes and not to miss critical points. Outside expertise should be sought when necessary.

Auditors should adhere to audit ethics and etiquette. They should be courteous, independent from the audited organization, and base their judgments on facts and evidence only. It is important to examine both the documentation and what is happening at the facility in order to see whether procedures are applied, whether controls are in place and to verify that the operators fully understand their responsibilities and obligation (i.e. 'do what is written and write what you do').

Auditors should plan their audits and, unless the audit is unannounced, notify the audited party of the plan and the regulatory or standard reference. Various audit methods may be used or combined.

One option is to start with a tour of the facility right after the opening meeting. The auditor follows the product path, from reception to shipment. Along the way, the auditor can make observations that will later be discussed in the meeting room with the documentation at hand. For example:

(a) The batch and specification numbers and the loading pattern of a lot being loaded on the conveyor are noted. The documentation for the specification is later checked.
(b) The name of a person reading dosimeters is noted. The job description, training record and tasks that the person is authorized to perform are later checked.
(c) The data on the calibration label of an instrument are noted. The calibration documentation of this instrument is later checked against the calibration schedule, the qualification of the person or organization having performed the calibration.
(d) The documentation related to damaged goods.

Another option is to select randomly a few irradiation lot numbers over the past months and from the data expand the checks. For example:

— Examine the dosimetry report, then the dose mapping for the particular item and the calibration for the batch of dosimeters that were used.
— Request the technical agreement for the particular customers.
— Note the timer setting used on the day of the treatment and cross-check with records of timer setting changes.

A common approach is to follow the sequence of requirements contained in a standard or regulation. This ensures a comprehensive review of the quality management system.

Whatever the method, the assessment for facility accreditation will cover:

(i) The irradiation equipment and the site.
(ii) The ability to conduct treatments, which depends on:
    — The skills and knowledge of the personnel;
    — The equipment available and its maintenance;
    — The existence and maintenance of a sound quality system.
(iii) The cleanliness of the premises and the safeguarding of product integrity.
(iv) An evaluation of risk from possible (re-)infestation or (re-)contamination following treatment.
(v) The control and the use of documentation and the keeping of records.

As part of the certification process, the operator of the facility needs to agree to immediately notify relevant authorities of any problems, concerns or irregularities in the treatments. Accredited facilities should be periodically re-audited.

Appendix I

AUDIT QUESTIONNAIRE

Appendix I is an example questionnaire intended to assist with gathering information prior to, or during, an audit of a food irradiation facility. The headings could also be used to structure a written audit report (see Box 1). It does not, however, provide guidance on specific phytosanitary applications of irradiation.

BOX 1. QUESTIONNAIRE STRUCTURE

(1) Food Irradiation Facility and Operator Details
(2) Product Information
(3) Regulatory Authority Control
(4) Radiation Source
(5) Dosimetry
(6) Food Irradiation Process Control
(7) Records and Documentation
(8) Packaging and Labelling
(9) Any Other Information

1. Food Irradiation Facility and Operator Details

1.1. What are the name and address of the facility?

1.2. What is the general layout of the irradiation facility, what conveyor system is used (if appropriate) and what is the size and type of irradiation container?

1.3. Is the facility designed to irradiate products continuously or batch-wise?

1.4. What is the legislation that the organization needs to comply with? [For example, national and international][4]

1.5. What is the management structure at the facility?

[4] Additional information is supplied in brackets.

1.6. What is the quality policy/strategy?
[For example, manuals, standard operating procedures and certifications]

2. Product Information

2.1 What type of food is irradiated?

2.2. What is the purpose of irradiation?

2.3. Is it unprocessed (raw) food, or has it been processed or manufactured?

2.4. Is any other treatment combined with irradiation of the product?

3. Regulatory Authority Control

These questions may only be necessary when the auditors are in facilities which are not in their home countries.

3.1. Which national regulatory authority(s) (including national plant protection organizations) are responsible for the following:

— Licensing the irradiation facility?
— Prior approval to irradiate food?
— Official control and audit of the facility?

[Useful information to gather includes: dates of regulatory visits, people met, time spent at the facility, any non-compliance found, written reports, reported remarks, deadlines for correction, corrective actions implemented and follow-up visits]

3.2. Which licences or permits have been issued for the irradiation of food? [It may be useful to obtain a copy of the licence, permit or official documentation relating to the official approval to irradiate food]

3.3. What official control and supervision does the regulatory authority perform?

4. Radiation Source

4.1. What type of ionizing radiation is used to process the food?
[For example, gamma ray, electron beam and X ray]

For radionuclide sources

4.2. Which radionuclide is used?
[For example, ^{137}Cs or ^{60}Co]

4.3. What is the current activity of the radionuclide source (in Bq or Ci)?

4.4. When was the last replenishment, when and how much was the loading?

4.5. How is the radiation source stored when not in operation (e.g. water pool or dry store)?

4.6. Is there a positive indication of the correct operational and the correct safe position of the radiation source, and is it interlocked with the product movement system?

For machine sources

4.7. Which type of machine source is used (e.g. electron accelerator)?

4.8. What is the maximum energy level (in MeV)?

4.9. What is the beam power?

4.10. Are beam parameters, such as voltage, current, scan speed, scan width, pulse repetition and transportation speed, recorded continuously?

4.11. Is there a positive indication of the correct setting of all machine parameters, and is the operation of the machine source interlocked with the product movement system?

5. Dosimetry

5.1. What types of dosimeter are used for dose validation and routine dose measurements?
[Are the dosimeters suitable for the application, and has the impact of environmental conditions (e.g. low temperature for frozen foods) on dose reading been accounted for?]

5.2. How are dosimeters calibrated, and is the dose traceable to a national standard?

5.3. What is the uncertainty in the dose measurement?

5.4. Are reference dosimeters used to verify the calibration of dosimeters?

5.5. What procedure is used for dose validation?

5.6. What is the position and magnitude of minimum and maximum dose in the product to be irradiated?

5.7. What is the dose uniformity ratio?

5.8. Have doses been determined for a reference location on the irradiation container? If so, what is the association between the reference location and:

(i) The minimum dose?
(ii) The maximum dose?

5.9. What is the frequency of the dose measurements when food is irradiated? [For example, do the first and last irradiation containers have dosimeters, and do a fixed number of irradiation containers in between the first and last irradiation containers also have dosimeters? What is the minimum number of dosimeters in the irradiator at any one time?]

5.10. Has dose mapping been performed for each product?
[Is this mapping representative for the intended dose, packaging, density or for any partial loads (partially filled irradiation containers)?]

5.11. During dose mapping, was the orientation or configuration of the load recorded?

5.12. Was this information used to produce a loading diagram?
[Does the loading configuration diagram reflect the loading during the dose mapping exercise?]

5.13. Has the irradiator been requalified when modifications were made to the source (strength/type/geometry), the conveyor or product (density/geometry)?

5.14 Is the radiation dose for foodstuffs given in fractional doses?

6. Food Irradiation Process Control

Product

6.1. Have all the process variables been identified?

6.2. Is the product to be treated fit for irradiation?

6.3. Is the food product prepacked, or is it treated in bulk?

6.4. What are the characteristics of the packaging material (suitability, hygienic condition, transport and handling)?

6.5. Are there standard operating procedures and quality assurance procedures in place to control the irradiation of food?
[Are they are up to date, accurate and cover all relevant aspects? Are they used by the operator? What evidence is there that people use these procedures? It may be useful to obtain copies of these documents]

6.6. What measures have been taken to ensure that treated and untreated foods are separated at all times?

6.7. Are colour change indicators used to indicate whether a product has been irradiated? Are they suitable for the application?

6.8. How is the product tracked through the process?

6.9. How are process parameters such as conveyor speed, dwell time, source exposure time or beam parameters monitored and recorded during operation of the facility?

6.10. How are the different process control instruments calibrated?

6.11. How is the temperature range of foodstuffs monitored (i.e. frozen foodstuffs) during treatment and storage?

7. Records and Documentation

Product traceability

7.1. What is the format and content of records kept for each batch of treated food?
[For example, nature and type of product being treated, packaging identification marks or shipping details, bulk density, type of source or electron machine, dosimetry, dosimeters used (calibration details) and date of treatment]

7.2. How long are records kept and in what form?

7.3. What documentation accompanies irradiated food destined for export?

7.4. What are the details of labelling used to identify the product or details of shipping documentation?

Process control

7.5. What records are maintained for each irradiation batch of food?

Dosimetry

7.6. What records are kept of dosimetry measurements?
[For example, archives, calibration log, calibration schedule and other records]

Personnel training

7.7. What are the qualifications of those responsible for validation, routine control, operation and maintenance of the facility?
[For example, academic qualifications, formal training and work experience]

8. Packaging and Labelling

8.1. What is the labelling of the prepackaged foodstuffs?
[For example, are they labelled as 'irradiated' or 'treated with ionizing radiation'? Are any special logos used (e.g. Radura)? Is the name of the food clear, is there a list of ingredients, a date of minimum durability, the name and address of the manufacturer/packager? Are there any special storage instructions or any instructions for use?]

8.2. What shipping documents are used?
[Do these documents state that the food is irradiated? Do they identify the irradiation facility in some way, do they include the date of irradiation treatment, do the papers identify the food and the lot or batch number of the food products?]

9. Any Other Information

9.1. Record any observations which may be appropriate in terms of food safety.
[For example, rodent control, general hygiene, washroom facilities, administrative control and any general observations]

Appendix II

CHECKLIST FOR THE APPROVAL OF A FACILITY IRRADIATING FOOD FOR PHYTOSANITARY PURPOSE

This checklist is based on annex 2 of ISPM No. 18 [21], which is a prescriptive part of the standard. The following checklist is intended to assist persons inspecting or monitoring facilities seeking to establish or maintain facility approval and certification of irradiated commodities for international trade. The failure to receive an affirmative response to any item should result in the refusal to establish, or the termination of, an approval or certification.

Criteria	**Yes**	**No**
1. Premises		
Irradiation facility meets the approval of the national plant protection organization (NPPO) with regard to phytosanitary requirements, and the NPPO has reasonable access to the facility and appropriate records as necessary to validate phytosanitary treatments		
Facility buildings are designed and built to be suitable in size, materials and placement of equipment to facilitate proper maintenance and operations for the lots to be treated		
Appropriate means, integral to the facility design, are available to maintain non-irradiated consignments and/or lots separate from treated consignments and/or lots		
Appropriate facilities are available for perishable commodities before and after treatment		
Buildings, equipment and other physical facilities are maintained in a sanitary condition and in repair sufficient to prevent contamination of the consignments and/or lots being treated		

Criteria	Yes	No
Effective measures are in place to prevent pests from being introduced into processing areas and to protect against the contamination or infestation of consignments and/or lots being stored or processed		
Adequate measures are in place to handle breakage, spills or the loss of lot integrity		
Adequate systems are in place to dispose of commodities or consignments that are improperly treated or unsuitable for treatment		
Adequate systems are in place to control non-compliant consignments and/or lots and when necessary to suspend facility approval		
2. Personnel		
The facility is adequately staffed with trained, competent personnel		
Personnel are aware of requirements for the proper handling and treatment of commodities for phytosanitary purposes		
3. Product handling, storage and segregation		
Commodities are inspected upon receipt to ensure that they are suitable for irradiation treatment		
Commodities are handled in an environment that does not increase the risk of contamination from physical, chemical or biological hazards		
Commodities are appropriately stored and adequately identified, procedures and facilities are in place to ensure the segregation of treated and untreated consignments and/or lots, and there is a physical separation between incoming and outgoing holding areas where required		

Criteria	Yes	No
4. Irradiation treatment		
The facility is able to perform required treatments in conformity with a scheduled process, and a process control system is in place providing criteria to assess irradiation efficacy		
Proper process parameters are established for each type of commodity or consignment to be treated, and written procedures have been submitted to the NPPO and are well known to appropriate treatment facility personnel		
Absorbed dose delivered to each type of commodity is verified by proper dosimetric measurement practices using calibrated dosimetry, and dosimetry records are kept and made available to the NPPO as needed		
5. Packaging and labelling		
Commodity is packaged (if necessary) using materials suitable to the product and process		
Treated consignments and/or lots are adequately identified or labelled (if required) and adequately documented		
Each consignments and/or lot carries an identification number or other code to distinguish it from all other consignments and/or lots		
6. Documentation		
All records about each consignment and/or lot irradiated are retained at the facility for the period of time specified by relevant authorities and are available for inspection by the NPPO as needed		
The NPPO has a written compliance agreement with the facility		

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DEFINITIONS

The definitions given below may not necessarily conform to definitions adopted elsewhere for international use.

calibration. A set of operations that establishes, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

commodity. A type of plant, plant product or other article being moved for trade or other purpose.

contamination. The presence of an unwanted material.

correction. An action to eliminate a detected non-conformity. A correction can be made in conjunction with a corrective action.

corrective action. An action to eliminate the cause of a non-conformity or other undesirable situation. There can be more than one cause of non-conformity. Corrective action is taken to prevent recurrence, whereas preventive action is taken to prevent occurrence. There is a distinction between correction and corrective action.

customer. An organization or person that requests the irradiation treatment of a product to the irradiator operator under specified requirements.

dose. The term dose refers to absorbed dose. Dose is the quantity of ionizing radiation energy imparted per unit mass of a specified material. The unit of absorbed dose is the gray (Gy), where 1 Gy is equivalent to the absorption of 1 joule per kilogram.

dose distribution. The spatial variation of absorbed dose throughout the process load, integrated over a complete treatment. The extreme values are the maximum dose (D_{max}) and the minimum dose (D_{min}).

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

dose uniformity ratio (DUR). The ratio of the maximum absorbed dose to the minimum absorbed dose (D_{max}/D_{min}) within a process load.

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

dosimetry. A measurement of absorbed dose by the use of dosimeters.

dosimetry system. The procedures and interrelated elements used for determining absorbed dose, including dosimeters, instruments and associated reference standards.

dwell time. The time interval during which a process load is at rest at an irradiation position in a shuffle–dwell irradiator, which is an irradiator in which a process load moves discontinuously past the irradiation source, alternately being moved (indexed) to a new irradiation position and then remaining at rest for a specified period at that position.

food irradiation. The process of exposing food to ionizing radiation to improve its safety and quality.

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

fractional dose. A portion of the intended total dose.

good manufacturing practice. A 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.

Hazard Analysis and Critical Control Point (HACCP). A system which identifies, evaluates, and controls hazards which are significant for food safety.

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

irradiation. The process of exposing material to ionizing radiation.

irradiation container. The holder in which product is transported through the irradiator. The holder can be a carrier, cart, tray, product package, pallet, tote or other container.

irradiation facility. The establishment where the irradiation process is performed. There are different types of irradiation facility depending on the irradiator type, the radiation source, the conveyor system and the operating mode. An irradiation facility consists of an irradiator, shipping and receiving docks, storage zones for irradiated and non-irradiated products, conveyor system, safety systems and the infrastructure for personnel and facility services including record control.

irradiator. The assembly of equipment and its housing where product is exposed to ionizing radiation. The irradiator provides for safe and reliable radiation processing and includes the source of radiation and associated mechanisms together with the conveyor, safety devices and biological shield.

irradiator operator. An organization or body responsible for irradiating the product.

loading configuration. The defined arrangement of product (food) placed in or on the irradiation container. Dose mapping is carried out for a particular loading configuration and this loading configuration is replicated to ensure consistent irradiation of product.

non-conformity. The non-fulfilment of a requirement.

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

performance qualification. The 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.

phytosanitary measure. Any legislation, regulation or official procedure having the purpose to prevent the introduction or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests.

preventive action. An action intended to eliminate the cause of a potential non-conformity or other undesirable potential situation. There can be more than one cause for a potential non-conformity. Preventive action is taken to prevent occurrence, whereas corrective action is taken to prevent recurrence.

process interruption. The intentional or unintentional stoppage that acts to prevent the irradiation process from proceeding continuously.

process load. Material with a specified loading configuration irradiated as a single entity.

process parameter. A specified value for a process variable. The specification for a process includes the process parameters and their tolerances.

process variable. A parameter within a food irradiation process that can be altered in magnitude and by doing so changes or alters the process effectiveness. Examples include conveyor speed and source position.

radiation sensitive indicator. Material which may be affixed to, or printed on, the process load and which undergoes a visual change when exposed to ionizing radiation. These indicators do not provide a quantitative measure of dose and may not work or be unreliable at low doses (e.g. in the dose range employed for phytosanitary treatments).

radiation source. A device that emits ionizing radiation.

radionuclide. The radioactive isotope of an element (e.g. ^{137}Cs or ^{60}Co).

regulated pest. A quarantine pest or a regulated non-quarantine pest.

re-infestation (phytosanitary). The renewed presence, in a commodity, of a living pest of the plant or plant product concerned. Re-infestation includes re-infection.

re-irradiation. The irradiation at any dose of a product or a portion of a product that was previously irradiated at the full intended dose.

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

sanitary. Of conditions affecting health. In this publication, sanitary relates to human health.

specification. An approved document stipulating requirements.

standard operating procedure (SOP). A written document that relates to a procedure or process, and details all the steps and activities necessary to achieve the expected outcome.

timer setting. When considering a shuffle and dwell process as opposed to a continuous conveyor process like X ray or electron beam, the timer setting is the set point in minutes and seconds that a tote, carrier or pallet spends in each 'dwell' position around the source. See also **dwell time**.

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

treatment (for phytosanitary purposes). An official procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization.

uncertainty in the dose measurement. A parameter associated with the result of a measurement that characterizes the dispersion of values that could reasonably be attributed to the measure.

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

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