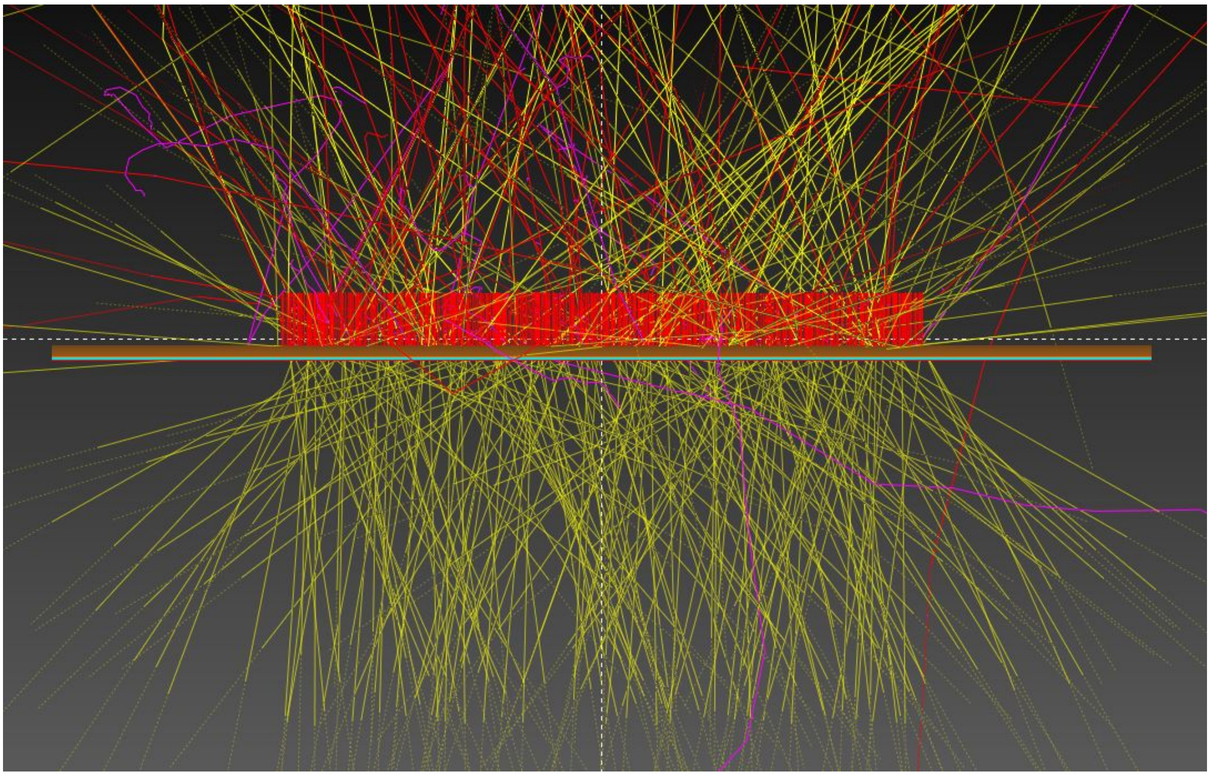
Joint FAO/IAEA Division
Nuclear Techniques in Food and Agriculture

TECHNICAL SPECIFICATION FOR AN X-RAY SYSTEM FOR THE IRRADIATION OF INSECTS FOR THE STERILE INSECT TECHNIQUE AND OTHER RELATED TECHNOLOGIES



Cover graphic: Monte Carlo simulation of X ray production. The gold target is shown in brown, backed by the cooling water in blue. The incident electrons are red and the X ray photons yellow. High energy scattered electrons are in magenta. © Dr Josef Mittendorfer.

TECHNICAL SPECIFICATION FOR AN X-RAY SYSTEM FOR THE IRRADIATION OF INSECTS FOR THE STERILE INSECT TECHNIQUE AND OTHER RELATED TECHNOLOGIES

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Preface

This document is organised to help the reader to understand various aspects of radiation technology, including requirements and specification for an X-ray system for the irradiation of insects for the SIT.

The introduction and radiation technology sections give some history of the use of ionising radiation and physics of radiation for understanding the requirements that follow.

This is then followed by discussion on radiation and electrical safety requirements to protect the operators, workers and public in general.

Following that is a brief discussion of a few issues related to the operation of a self-contained X-ray irradiator that differ from those of a gamma irradiator, and hence need some emphasis.

This is followed by discussion on key variables of the X-ray irradiator which need to be addressed during the design and construction stage of the irradiator.

The last section is a short description of the objective and tests that should be carried out by the manufacturer at the customer site after commissioning of the irradiator. This includes the crucial operational qualification phase, where data are collected as evidence that the irradiator meets the specifications laid out by the IAEA.

Lastly, the Appendix contains a list (non-exhaustive) of several relevant national and international standards that should be helpful for designing and constructing the irradiator and for determining its operational procedures.

Contents

Introduction

Ionising radiation

The energy associated with radiation is inversely proportional to the wavelength; the longer the wavelength, the lower the energy. The energy associated with X radiation and gamma radiation is greater than the binding energy of an atomic electron, thus this type of radiation can ionize an atom or break the molecular bonds. Radiation with such high energy is referred to as 'ionising radiation'. Besides gamma radiation and X radiation, ionising radiation includes high-energy electrons (generally >80 keV). Ionising radiation breaks down molecules, modifying chemical, physical or biological properties of the irradiated material. Thus, radiation can cause polymerisation of plastics, kill pathogens and microorganisms, and damage DNA molecules, leading to applications in industry and food processing, sterilisation of health care products, and reproductive sterilisation of insects for the SIT.

There are three types of ionising radiation generally used in radiation processing, namely gamma radiation, X radiation and electrons. All have generally similar effects on the irradiated materials (since they have similar relative biological effectiveness), and in particular on the irradiated insects (Bakri et al. 2005b).

Entomology applications

There are a number of applications of ionising radiation in entomology (Bakri et al. 2005a), including disinfestation of commodities for quarantine and phytosanitary purposes, and reproductive sterilisation of insects for pest management programmes using the Sterile Insect Technique (SIT) (Dyck et al. 2005). Radiation can also be applied in various ways to facilitate the use of biological agents for control of arthropod pests and weeds (Carpenter 2000; Goettel 2009; Greany and Carpenter 1999), such as irradiation of hosts to prevent emergence of the host and of factitious hosts to suppress host immunity.

Irradiation of insects is a relatively straightforward process with reliable quality control procedures (FAO/IAEA/USDA 2014). The key parameter is the absorbed dose of radiation; efficacy of the irradiation process is guaranteed as long as the dose is correctly delivered (Bakri et al. 2005b). Other advantages of using radiation (gamma radiation, X radiation and electrons) include (1) insignificant increase in temperature during the process, (2) treated insects can be used immediately after processing, (3) irradiation does not add residues that could be harmful to human health or the environment, and (4) radiation can pass through packaging material, thus allowing the insects to be irradiated after packaging.

Radiation technology

Energy transfer from radiation to matter

Ionising radiation is classified under two categories: directly ionising radiation and indirectly ionising radiation (Attix et al. 1968). Charged particles such as electrons belong to the first category since they can transfer energy directly and ionise the atoms of the irradiated matter (e.g. tissues, insects). On the other hand, uncharged particles like photons (gamma radiation and X radiation) transfer energy indirectly by first transferring their energy to electrons, which in turn ionise the atoms. The nature of this energy transfer from radiation (photons and electrons) to the irradiated matter influences the distribution of dose (IAEA 2002; McLaughlin et al. 1989). Dose distribution (or dose variation) in the irradiated matter is an important variable for insect irradiation.

When matter is irradiated with a photon beam, the intensity of the beam, and thus the dose imparted to the irradiated matter, decreases with depth as radiation penetrates into the matter. The rate of decrease in the intensity depends on the photon energy, composition and density of the irradiated material, and irradiation geometry. Tables of the mass attenuation coefficients (amount by which the photon beam is attenuated) and mass energy-absorption coefficients (energy absorbed by the material irradiated) are provided by NIST (Hubbell & Seltzer 1996) for elements and selected compounds and mixtures over the range of energies from1 keV to 20 MeV.

Radiation dose

The absorbed dose, D, is radiation energy absorbed in a unit mass of a material, and is mathematically expressed as the quotient of $d\varepsilon$ by dm, where $d\varepsilon$ is the mean energy imparted to matter of mass dm; thus, $D = d\varepsilon/dm$ (ICRU 2011). The unit is J/kg. The special name for the unit is gray (Gy); thus, 1 Gy = 1 J/kg. The unit of absorbed dose used earlier was rad (1 Gy = 100 rad). Quite often, 'absorbed dose' is simply referred to as 'dose'.

Radiation energy

To maintain fitness of the irradiated insects and for the safety of the operating personnel, induction of radioactivity in the irradiated materials, such as canisters (reusable containers) and insects, must be avoided. This is achieved by restricting the energy of the radiation used for treating insects as follows (Codex Alimentarius 2003a; Codex Alimentarius 2003b; FAO/IAEA/WHO 1999):

- for photons, the energy should be less than 7.5 MeV, and
- for electrons, the energy should be less than 10 MeV.

Thus, gamma radiation from cobalt-60 (photon energies are 1.173 and 1.332 MeV) and caesium-137 (0.662 MeV), electrons generated by accelerators with energy less than 10 MeV, and X radiation generated from electrons with energy below 7.5 MeV are acceptable for irradiation of insects.

Gamma irradiators

To expose insects to gamma radiation, they are treated in a gamma irradiator, which consists of an isotopic radiation source, a mechanism for transporting the insects through the radiation field, and an operating system to control the exposure of insects to radiation.

More than 1000 different radioisotopes emit gamma radiation, but only two are used for radiation processing, namely cobalt-60 and caesium-137. Both have well determined half-lives, emit relatively high-energy gamma rays, and decay into stable isotopes. Both radioisotopes are produced in nuclear reactors.

There are two types of gamma irradiators: small self-contained irradiators and large panoramic irradiators. Self-contained irradiators are specially designed for research and for applications that need small doses and relatively small throughputs, such as blood irradiation to help prevent transfusion-induced graft-versus-host disease (GVHD) and exposure of insects for pest management programmes. Most irradiation of insects is currently carried out in such irradiators. These irradiators house the source within a protective shield of lead or other material; thus, they can be placed very conveniently in an existing laboratory or a room without needing extra shielding (hence, self-contained). The advantages of such small irradiators are that they provide a high dose rate and good dose uniformity within the irradiated sample, which is essential especially for radiation research. These characteristics are achieved by surrounding the sample with several radiation source pencils, such that it receives radiation from all directions.

Low-energy X-ray irradiators

Recently it has become increasingly difficult to purchase and transport such small-scale self-contained gamma irradiators; for example, Nordion stopped manufacturing their self-contained cobalt-60 irradiators. Also, the international transportation of radioisotopes has become problematic. This has led the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture to look for other types of irradiators that can be suitable for SIT programmes. Based on the general requirements of the

SIT programmes, such as easy to locate in an insect rearing facility, easy to operate with minimal training and ability to operate continuously for several hours, it seems reasonable that low-energy X-ray irradiators could be suitable for the current purpose.

Since such irradiators do not depend on an isotopic source for the production of radiation, the danger of them being misused is eliminated, which seems to be the primary drive behind the move to replace gamma irradiators with X-ray irradiators (National Academy of Sciences 2008).

A low-energy X-ray irradiator consists of a high voltage power supply, an X-ray tube, and a device to transport the insect canisters through the X-ray field. The X-ray tube nominally consists of an electron emitter, a converter to produce X radiation from these electrons and a cooling mechanism for the converter.

Since low-energy self-contained X-ray irradiators are a recent innovation, it may be informative and useful to compare and learn from the self-contained gamma irradiators. In some cases, they are quite similar, such as radiation safety requirements, while for some other aspects they may be quite different, such as reliability of operation, cooling requirements, mode of operation and procedure for delivering a desired dose. These are discussed below.

Radiation Safety

An irradiator should be designed to keep the radiation exposure and dose to workers ‘as low as reasonably achievable’ (ALARA), and within predetermined levels. These dose limits are based on the recommendations of several agencies of the United Nations (UN), including the International Atomic Energy Agency (IAEA), Food and Agriculture Organization of the United Nations (FAO), and World Health Organization (WHO) (IAEA 2010; IAEA 2014). Appropriate safety methods and procedures have been developed for each type of irradiator, and when operated correctly with the appropriate safeguards, they are safe and easy to use. Gamma irradiators are usually licensed by national atomic energy authorities, which set requirements such as restricting access to certain areas and authorised persons, a periodic survey of the radiation field in the vicinity where workers could be present, the use of personal radiation dosimeters, and the availability of radiation survey meters. On the other hand, electron accelerators and X-ray units are generally regulated by occupational safety and health agencies, which also require operator training, etc., and may require use of personal dosimeters. All these requirements are specifically aimed at protecting the workers from radiation. In addition, irradiator design should incorporate interlocks that prevent unintentional access to areas with high-radiation fields.

There are available specific guidelines for safety issues for self-contained gamma irradiators (ANSI 2007) but there are currently no specific guidelines available for low-energy X radiation. However, it is reasonable to assume that the safety requirements concerning self-contained gamma irradiators could apply here. The following discussion is based on a published report by the American National Standards Institute, Inc. (ANSI 2007). For such an irradiator the radiation source is completely contained at all times in a dry container constructed of solid materials, such that human access to the source and the volume undergoing irradiation is not physically possible in its design configuration.

The safety of an irradiator depends mainly on its construction, design, installation and operation and maintenance. Responsibility for the safe design of the irradiator, including interlocks, controls and primary shielding lies with the manufacturer.

The maximum permissible equivalent dose rates are given in Table 1.

Radiation survey: It is recommended that a radiation survey is performed on the irradiator by the manufacturer, *before* shipment, to establish compliance with applicable regulations. After installation of the irradiator at the facility and before its use, a verification survey should be performed and

Table 1. Maximum permissable surface radiation levels.

Location	**Maximum permissible radiation levels**	
	Unrestricted area	Restricted area
1 m from accessible surface*	0.002 mSv h^{-1}	0.02 mSv h^{-1}
30 cm from accessible surface	0.005 mSv h^{-1}	0.05 mSv h^{-1}
5 cm from accessible surface	0.02 mSv h^{-1}	0.2 mSv h^{-1}

* accessible surface is that surface of the irradiator to which human access is possible without the use of tools or without penetration of the structural radiation shield

documented. A survey shall be repeated if any significant changes are made to the irradiator (such as an installation of a new X-ray tube for an X-ray irradiator).

Radiation monitor and alarm system: It is recommended that a fixed monitor is available to detect the radiation level around the irradiator. The monitor should be able to detect the radiation level above a set point, which is set as low as practical. There should be visible as well as audible signal if the radiation level exceeds the set point. The monitor should have a back-up power supply independent of the irradiator.

Safety interlocks: Safety interlocks should be designed to prevent radiation levels in excess of those listed above under all conditions. Redundancy should be considered in the design of these interlocks. The irradiator shall not be capable of starting until all radiation shielding is in place. Movable radiation shielding, such as an access door for placing the insect canisters for irradiation, shall be interlocked so that the irradiator cannot be started in an un-safe mode.

Electrical Safety

High voltage electrical installations (and subsequent major augmentations) must be designed and constructed to a standard consistent with good industry practice, with careful consideration of the ongoing safety of personnel and members of the public, integrity of equipment and risks to property. When designing such installations, consideration must be given to a range of issues, such as:

- insulation levels to withstand the highest voltages,
- methods of installation of equipment, cables and accessories, and
- provision of earthing such that the system operates under all conditions and ensures safety of human life where there is legitimate access.

Before any high voltage installation work can be connected to a power supply, the person intending to make the connection must:

- inspect the work,
- be satisfied that tests have been carried out to ensure the electrical safety, the compatibility with the supply system, and the correct polarity, phase rotation and protection of the supply, and
- verify the technical safety compliance of the supply.

The owner must keep records and plans of the installation.

X-ray Irradiator Operation

Since the radiation source in an X-ray irradiator is quite different from than in a gamma irradiator, the operation of the former differ at least in five aspects:

- reliability of operation,

- mode of operation,
- cooling of the X-ray tube,
- radiation energy spectrum, and
- procedure for delivering a desired dose.

Reliability of operation

Reliability of operation of an irradiator is one of the key elements requiring attention. For a gamma irradiator, the radioactive source never fails, and thus radiation is always available when needed. For an X-ray irradiator, however, reliability becomes a central issue. Of course, one of the problems would be the availability of a stable power supply, especially in developing countries. But assuming that it is not a major problem, the integrity of the X-ray tube as well as that of the high voltage power supply is of major concern. Reliability becomes a crucial issue when the irradiator is used in a production mode. For example, in SIT applications the insects are irradiated at a specific time during their development and then are released within a certain time duration. During release operations this process cannot be interrupted for a significant length of time. Reliability could, of course, be enhanced if the irradiator can be serviced promptly. The manufacturer should supply reliability data, including but not limited to mean time between failures and estimated availability from actual experience or calculation based on realistic assumptions of the reliability of each of the components in the system. Essential spare parts based on the reliability analysis as well as trained staff to carry out the necessary modification and repairs should be available to the operation location on a timescale compatible with the usage of the machine.

Thus, spare parts and staff training should be considered during the procurement procedure to ensure high availability of the irradiator.

Mode of operation

Unlike a gamma irradiator, an X-ray irradiator has more parameters to choose for a specific irradiation run. For a gamma irradiator, in principle, the time duration of exposure is the only variable to select to deliver a desired dose to the insects. On the other hand, for an X-ray irradiator, dose depends also on the tube voltage and tube current. Because of this, it is recommended that these values are password protected. One way of doing this would be to have two types of operations: one for the supervisor who has the password, and the other one for the operators. The supervisor can lock a set of parameters for a specific irradiation; this can be done for several different types of irradiations (sets). The operator then can load the canisters in the irradiator and select the appropriate set depending on the supervisor’s instructions and expose the insects.

Cooling the X-ray tube

At the low electron energies suitable for a self-contained irradiator, the conversion efficiency for X radiation is quite low. Thus, a large proportion of the energy of the electrons is absorbed by the converter which raises its temperature. For safe and efficient operation, this heat is generally removed by circulating a liquid surrounding it, most generally water. Designing such a cooling system, it is quite critical to keep in mind that such an irradiator could be located in a geographical region where the outside ambient temperature is as low as -20 ºC or as high as 50 ºC.

Radiation energy spectrum

The radioisotope used in a gamma irradiator is generally cobalt-60 or caesium-137. Both of these isotopes emit either one or two photons of discrete energy. Thus, the radiation energy spectrum that a product/sample is exposed to in a gamma irradiator is generally mono-energetic, with a small fraction of low energy Compton scattered photons. On the other hand for an X-ray irradiator, since the photons are generated through the bremsstrahlung process, the radiation is a spectrum of energy where the maximum energy is that of the electrons, while the minimum energy is about 30-40 keV, depending on the design of the X-ray tube including any inherent filtration. Thus, the spectrum changes with the tube voltage, mainly at the high energy end of the spectrum. The lower energy photons are absorbed more quickly delivering a higher dose near the entrance surface and progressively changing the photon spectrum; thus influencing adversely the dose uniformity within the insect canister.

Procedure for delivering a desired dose

To deliver a required dose, one selects ‘irradiation time’ for a gamma irradiator since the dose rate is constant during that time period. For an X-ray irradiator, on the other hand, the dose rate would depend on tube voltage and current, which could fluctuate or even go to zero momentarily if the tube arcs.

To mitigate this, it is recommended that an irradiation run for an X-ray irradiator is set for a given energy output of the power supply of the irradiator (namely kW• s) instead of time (as in the case of a gamma irradiator). The dose rate in a gamma irradiator is proportional to the radioactivity of the source, while for an X-ray irradiator dose rate is proportional to the power output of the power supply (namely kW) for a fixed tube voltage. Thus, we can define the ‘dose energy ratio’ as the ratio between the dose at a reference location (in Gy) and the energy output of the power supply of the X-ray irradiator (in kW• s), the value depending on the voltage (Mehta and Parker 2011). This ratio needs to be determined during the operational qualification procedure (see below). Knowing this ratio, a set value of the energy output of the power supply (kW• s) can be used for an irradiation run to deliver a desired dose. For this procedure to work, the irradiator control system must be able to integrate kW• s as the run progresses, and to terminate it when a set value is reached.

Technical parameters

General

There are several characteristics associated with an irradiator that are of interest for any intended application. Such key characteristics relevant to insect irradiation include:

- throughput,
- dose rate,
- canister size, and
- dose uniformity.

These are of course interrelated with each other. The two principal ones could be throughput and dose uniformity within an insect canister. Throughput is directly related to insect canister size, number of such canisters and dose rate, while the dose uniformity depends on the canister size, its composition and the irradiation geometry (physical arrangement of the canisters and the X-ray tube).

Dose rate

There is some limited data that show that low dose rates reduce the adverse effect of radiation on the insects (Bakri et al. 2005b). However, the range of values of concern here may be too little to cause any dose-rate influence. The dose rate at the location of the insect canisters determines how long it will take to deliver a required dose, and thus the throughput. If the dose rate is too small, the long treatment time will result in a low and, depending on the size of the insect facility, uneconomical throughput. On the other hand, if the dose rate is too high, the canisters will have to be in the irradiation position for a very short time, which will make it difficult to consistently give the correct dose. Thus, there is in essence a window (albeit a wide one) of dose rate that is suitable for the process.

Dose rate for a low-energy X-ray irradiator depends on the power input to the tube; thus, it would depend on the tube voltage and the tube current. This dependence is linear for the current (I); however, it is quadratic for the tube voltage (V). Thus, $\text{dose rate } \propto \mathrm{k} \times V_{\mathrm{c}}^{2} \times I$, where k is a constant depending on several variables, including the location of the measurement. V_{c} is the adjusted voltage, generally $V_c = V\text{-}V_0$; where V_0 is about 50 kV, but may depend on the specific tube design. As a general practice, during insect irradiation, one would select the maximum tube voltage, and select the value of the current as per dose rate needed. It would most likely be the maximum value to maximize throughput.

Dose uniformity

The absorbed dose that is used to induce the required effect in insects is of prime importance to the pest management programmes that use these insects. As dose increases, the desired effect (for example, sterility level) increases; however, insect fitness will decrease. Thus, optimisation is necessary in selecting treatment dose to balance the desired effect and insect fitness, taking into consideration programme requirements (Parker and Mehta 2007).

In reality, because of the unavoidable dose variation within a canister, an acceptable range of dose to be given to the insects has to be defined according to the specific programme requirements. Most often, programmes or regulatory officials specify a minimum dose that all insects must receive to ensure sufficient sterility. Due to dose variability, most insects actually receive a dose that is somewhat higher than that minimum. Thus, it is essential that dose is fairly uniform within a canister; the goal is to expose all insects sufficiently without treating large proportions with doses that are high enough to substantially reduce their fitness. The uniformity in dose is generally characterised by the parameter referred to as dose uniformity ratio (DUR). This is the ratio of the maximum dose to the minimum dose within the insect canister. Its value is always more than unity; the smaller the value the better is the dose uniformity. The acceptable value depends on the application; for example, for sterilization of fruit flies for SIT, the recommended value is less than 1.3.

To a large extent, the dose uniformity in the canister depends significantly on the irradiator design. One of the important factors is the relative size, and positions of the canisters and the X-ray tube. Also, dose variation within the canister depends significantly on its size, besides the construction material of the canister walls. As mentioned earlier, the radiation reaching the insects has a spectrum of energy, and this affects the DUR. For example, low energy photons will deliver significantly higher dose to the insects at the entrance (near the canister walls). This could be mitigated by absorbing these low energy photons before they reach the insects. One method would be to include a filter material in the wall of the canisters. Yet another method to increase uniformity (decrease DUR) is by irradiating the canister from two or more sides (for example, by rotating the canisters).

Radiation dosimetry

Generally dosimetry is the responsibility of the user of the irradiator during its normal routine operation. However, during operational qualification (as described below) the supplier of the irradiator would need suitable dosimetry system(s) to determine the absolute value of the dose rate at a reference location, as well as to measure the dose distribution to determine DUR. It is thus envisaged that two types of dosimetry systems (not including the survey meters) may be needed: one would be a reference dosimetry system to determine the dose rate and the second would be a routine dosimetry system to measure dose distribution within the canister (thus, DUR). It is essential that these dosimetry systems are appropriately calibrated for the relevant energy and have traceability to national or international standards. A suitable reference dosimetry system could be an ionization chamber or an alanine/EPR system, each appropriately calibrated.

Receiving the irradiator

Before the irradiator is formally handed over to the client, the manufacturer should execute the following:

- commissioning,
- installation qualification, and

- operational qualification.

It is recommended that the staff of the facility participate in these activities.

Installation qualification: The objective of an installation qualification programme is to demonstrate that the irradiator with its associated processing equipment and measurement instruments have been delivered and installed in accordance with their specifications (ISO/ASTM 2013). Installation qualification includes documentation of the irradiator and the associated processing equipment and measurement instruments, establishment of the testing, operation and calibration procedures for their use, and verification that they operate according to specifications. This includes ensuring that the tube voltage and current are available over the entire range as specified. Another important aspect is to ensure that the energy input to the tube (in kW• s) is computed properly and that the irradiator can be run based on this quantity.

An effective installation qualification program will help ensure correct operation of the irradiator.

Operational qualification: Following installation qualification, it is essential that operational qualification is executed. The objective is to obtain and document evidence that the installed equipment and instrumentation operate within predetermined limits when used in accordance with operational procedures (ISO/ASTM 2013). This qualification process is quite vital to show that the irradiator meets all the set specifications.

Operational qualification establishes baseline data for evaluating facility effectiveness, predictability, and reproducibility for the range of conditions of operation for the key operating parameters that affect absorbed dose in the product.

Operational qualification includes:

- determination of the dose rate at a reference location for reference irradiation geometry (requiring a reference dosimetry system),
- measurement of the absorbed-dose distributions in reference homogeneous material(s) ─ this process is sometimes referred to as ‘dose mapping’; this exercise should determine DUR (requiring a routine dosimetry system),
- determination of the relationship between absorbed dose and various irradiator parameters, such as tube voltage, tube current and energy of the power supply (kW• s) (requiring a dosimetry system),
- establishment of the effect of a process interruption/restart, and
- establishment of consistency of operation by measuring the dose rate several times over a period of say one hour, shutting the irradiator between each measurement.

Conclusion

This report describes the requirements, including detailed technical specifications and physical requirements, for a self-contained X-ray irradiator that may be used for SIT applications and other related uses. It includes safety requirements, performance specifications, including tests to be conducted following the commissioning phase. These tests establish baseline data for evaluating facility effectiveness, predictability, and reproducibility for the range of conditions of operation for the key operating parameters that affect absorbed dose in the product. These tests provide the evidence that the irradiator meets the set specifications.

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Appendix: Selected Standards

This is a selected list of standards that may apply to X-ray equipment. It is not intended to be exhaustive.

Cabinet X-ray

- Performance standards for ionizing radiation emitting products − Cabinet X-ray systems, CFR - Title 21 - 1020.40 (national standard of the U.S.A.)
- Radiological protection standard for X-ray luggage inspection system, GBZ 127-2002 (national standard of China)
- Irradiation devices: X-ray devices for non-medical applications − General regulations, StrSchVO Part 4 § 83 (national standard of Austria)

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Electrical safety

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