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Proposed Regulatory Requirements for Operation and Maintenance of Gamma Irradiator Facility

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Abstract: Gamma irradiation facilities are in use for preservation of food products, sterilization of health care products, polymerization of wood, vulcanization of rubber and such purposes for which high intensity irradiation is required. However, ionizing radiation can also be harmful unless it is properly controlled. Industrial irradiators produce very high dose rates during irradiation, such that a person accidentally present in the radiation room could receive a lethal dose within minutes or even seconds. For the safety of human and environment, Special design and operation precautions are taken to avoid the exposure to gamma radiation which is continuously emitted by the radiation source. This paper proposes some of regulatory requirements related to gamma irradiator operation and maintenance. Such as, operator training, safety devices, interlocking, maintenance, control systems, power failure, and reporting.

Keywords: Gamma Irradiator, Operation Safety, Regulatory Requirements.

1. Introduction

Irradiation facilities have been used extensively for food irradiation studies, developing optimized radiation doses for medical product sterilization [1], and radiation effects evaluations on electronic components and other materials such as optical components (mirrors, lenses and windows) for space applications. In a large irradiation facility, the irradiation room where the product is treated with radiation is the focal point of the facility (Fig.1). Other major components of a commercial facility include [2]:

- Shielded storage room (dry or wet) for the radiation source rack (60Co);
- Source hoist mechanism;
- Radiation shield surrounding the irradiation room;.
- Control console (room);
- Product containers (totes);
- Product conveyor system through the shielding maze;
- Control and safety interlock system;
- Areas for loading and unloading products;
- Supporting service equipment.

The radiation source is either in the irradiation room (during irradiation of the product) or in its shielded storage water pool, it also known as wet storage. There is enough shielding provided water pool so that staff can work in the irradiation room (for example, for maintenance) when the source is in the storage pool. Water has several desirable characteristics when used as a shielding material, including that it is an easily available liquid, it is convenient to circulate for heat transfer and it is transparent. For a wet storage facility, nearly all materials used to construct the source rack, guide system and source containers are made of stainless steel so that galvanic corrosion is eliminated. Surrounding the irradiation room is the radiation shield, generally consisting of a concrete wall thick enough (usually 2 m) to attenuate the radiation emanating from the source so as to maintain the radiation level at the location of the control console at natural background level. The concrete wall is constructed as a maze in order to permit movement of the product and yet significantly reduce the scattered radiation reaching the control console, where the operator can control or monitor the movement of the source and the product [2]. The transport mechanism for the product can be simple or quite elaborate, depending on the irradiator design. For continuous irradiation (as shown in Fig. 1), the product containers are moved around the radiation source on a conveyor bed which passes through the maze. The irradiation facility also provides areas for storage of the unprocessed product as well as the processed product. It is a requirement that the design of the facility is such that these two types of product cannot be mixed inadvertently (note the separating fence in Fig. 1).

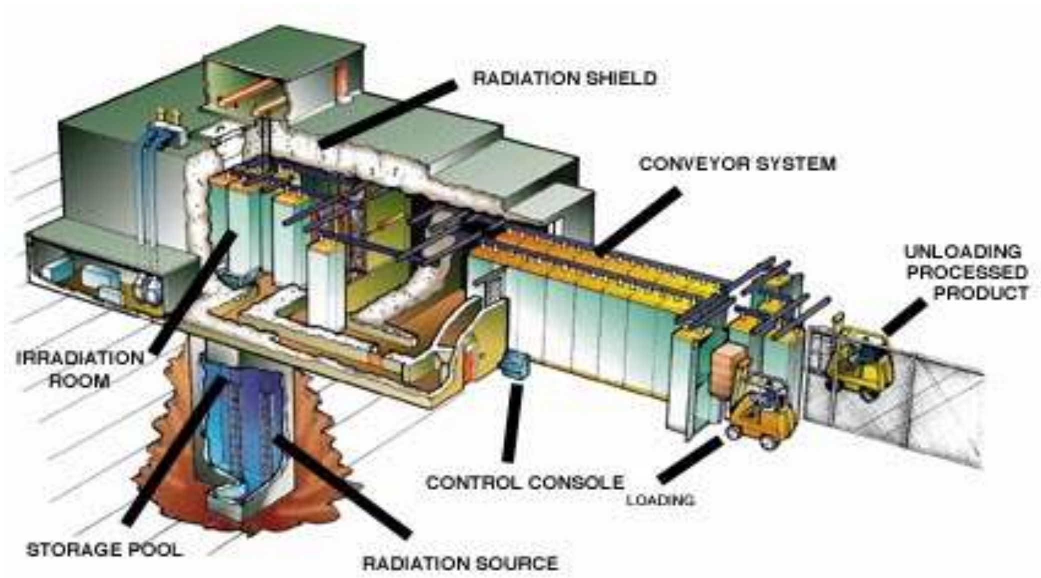

Fig. 1: Gamma Irradiator Facility

1.1. Idea of Food Irradiation

Bulk or packaged food passes through a radiation chamber on a conveyor belt. The food does not come into contact with radioactive materials, but instead passes through a radiation beam, like a large flashlight [3]. The type of food and the specific purpose of the irradiation determine the amount of radiation, or dose, necessary to process a particular product. The speed of the belt helps control the radiation dose delivered to the food by controlling the exposure time. The actual dose is measured by dosimeters within the food containers. Cobalt-60 and cesium 137are the most commonly used radionuclide for food irradiation.

2. Personnel Safety System

The goal of safety technology is to keep the potential hazards for man and the environment as low as possible by applying and utilizing the appropriate technology [4].Operators and other workers at the facility are a critical group that could be potentially exposed to high radiation levels. This is prevented through hinter locks and critical design features and operational procedures of their radiator. The main objectives for a safety system are:

1. keep people out of dangerous areas, warn people of hazards,
2. de fine procedures, for example
   – to se cure radiation rooms
   – to unsecure radiation rooms and allow access after a delay for ozone removal
   – for emergency stop and access violations
3. Provides a fety even when a single fault is undetected.

3. Safety Devices in a Gamma Facility

Implementing safety functions is based on safety devices, every safety function always encompasses the chain of the information acquisition through information evaluation up to executing the specific action as shown in Fig 2.Severalsafety systems are incorporated in the design of an irradiator that either give early warning of any potential problems or prevent them from occurring see Fig.3.There are many sensors which are used to monitor and control many safety parameters in gamma irradiator [2],[5]:

1. High temperature detector, to recognize abnormal heat buildup, which could lead to product damage and the increased potential for fire.
2. Pool water level sensor, to continuously monitor the water level in the storage pool and alerts the operator of

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unusually high or low levels.

3. Radiation monitor, to continuously monitor radiation level and alerts the operator if there is abnormal level; two most likely locations for these monitors are the product exit port and water deionizer tank. More radiation probes may be installed inside the irradiation room.
4. Source-down detector system, to provide direct indication of the position of each source rack when it reaches the bottom of the storage pool.
5. Earthquake detector, to provide a means of automatically returning the source to the safe storage position in the even to faseismic event.
6. Source guards and collision sensors, are used for jam detection and avoidance. Jammed product or jammed source racks playing a significant role in most irradiator incidents.

These systems are designed to protect product, facility, workers and in the worst case scenario the surrounding environment. These safety systems and devices are expected to meet certain criteria, including [5]:

1. Protection in depth – if one system fails there is yet another system (based on different principle) as a backup;
2. Redundancy and diversity–principal components should be duplicated;
3. Independence –fault in the irradiator should not impair the safety system; and
4. Fail-to-safe –failure of a safety system should always result in safe conditions.

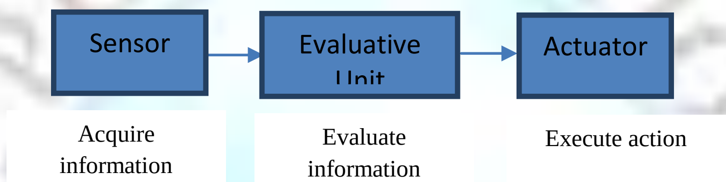

Fig. 2: Safety Function

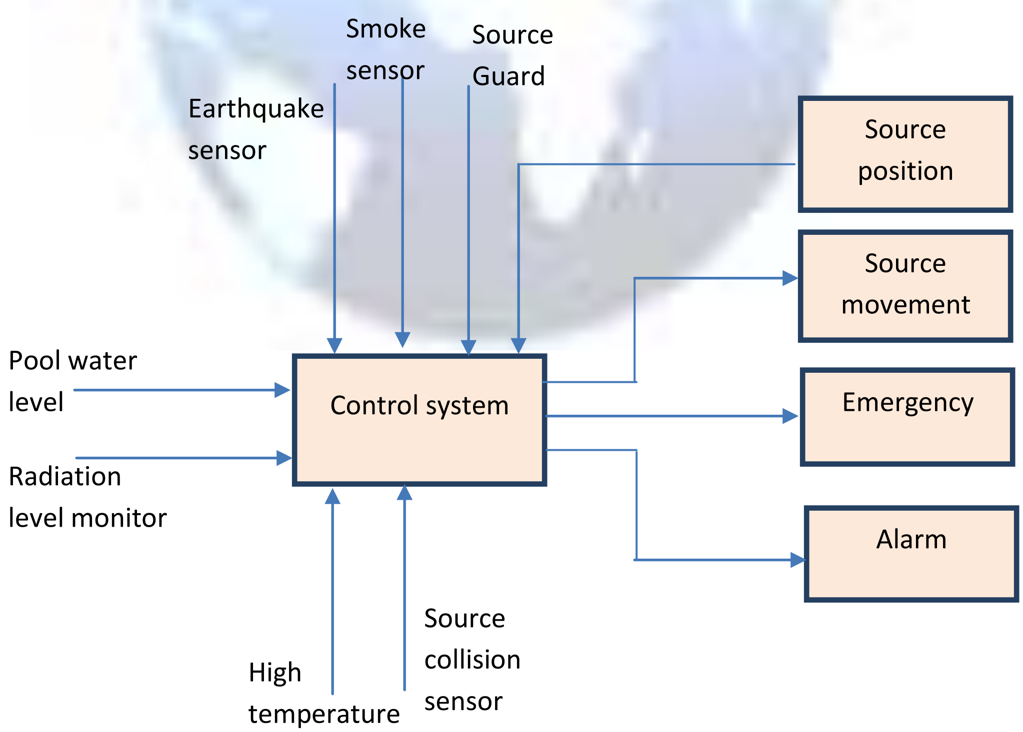

Fig.3: Instrumentation and Control System in Gamma Irradiator

3.1. Common safety devices [6]

3.1.1. Access control interlocks, are used to control access doors. Access doors are closed and locked until their radiation room is safe to enter. In the case of a force dentry, the safety system must move the radiation source to the storage room. Ozone time delay – when air is exposed to ionizing radiation, ozone and other toxic gases are formed, which decay quickly and are removed by the ventilation system. This safety system prevents entry in the irradiation room for a short time period, after the source has been moved to the shielded position, until safe level of these gases is reached.

3.1.2. Smoke sensors, Fire extinguishing systems–many fire alarms are caused by system malfunctions. Thus, it is important to build redundancy into the activation method for a fire extinguishing system. A single false activation of a water sprinkler system could cause more damage than the extra cost of a pre-action activation system or a gas extinguishing system.

3.1.3. Radiation measurement, radiation measurement equipment must be selected and used appropriately. The measurement range for instruments surveying workers areas should extend low enough to measure natural background radiation(0.1 µSv/h). If the dose rate exceeds several mSv/h, one would not expect to enter that area. The measurement equipment must be robust enough for the intended use. When a radiation survey meter is attached to the main entry key of the irradiation room, the instrument must be able to withstand some rough treatment. All instruments must be checked regularly for proper operation. In many cases, a check of proper operation is necessary before each use of the instrument. A check source that is permanently installed at an appropriate location can ease the frequent operation checks. Many countries require calibration for all instruments serving personnel safety.

3.1.4. Personnel dosimeter, the operators and workers wear radiation dosimeters (badges) during working hours to monitor the amount of radiation dose they receive. Typically, these badges are read every month to determine the dose received by the wearer of the badge. The radiation badges are thus used to confirm that no individual is receiving dose above specified limits.

4. Proposed Regulatory requirements

4.1. Licensing process

Generally, the applicant should submit the Final Safety Analysis Report (FSAR) along with Quality Assurance Manual (QAM) of the design and systems installed in the facility, to the regulatory body for review [7]. Based on the review of information provided in the FSAR, information obtained from inspections by the regulatory body, the trouble free performance of facility, radiation levels and dosimeter results within the acceptable limits, the regulatory consent in the form of license is issued by regulatory body. At each stage of replenishment/ addition to the source strength of the radiation facility, the licensee is required to obtain authorization for procurement of additional Co-60. After each source loading licensee shall obtain consent for resumption of routine operation. The Licensee is required to submit to the regulatory body periodic status reports. Unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed report within the prescribed period. The Licensee should operate the facility as per the requirements stipulated in the regulatory body Safety Code on Operation and Maintenance of Gamma Irradiators. The operating organization shall demonstrate to the competent authority how the design of the irradiation facility and related operational procedures will contribute to the prevention of accidents on die one hand, and to mitigation of their effects on the other. This information should be provided in the form of documented safety analyses describing and evaluating the predicted response of the plant to incidents (postulated malfunctions or failures of equipment, common cause failures, human errors, external events, etc.) which could lead to accident conditions. These analyses should be extended to relevant combinations of such malfunctions, failures, errors and events.

Safety procedures play an important role in preventing accidents. The procedures should cover at the minimum the following issues management responsibilities for licensing, insurance, training, radiation safety organization duties of a radiation safety officer definition of controlled and restricted areas access procedures to irradiation areas work procedures in irradiation areas workers health and personnel dosimeter use of measurement equipment accident prevention programme responding to emergencies and incidents receiving and shipping of radioactive material (e.g. gamma source, activated accelerator parts, etc.) maintenance and equipment modification disposal of radioactive waste. All radiation accidents have one feature in common: blatant disregard for procedures. Even an untrained worker (which should not exist) can worker a sonably safe as long as he follows procedures set by the facility or the manufacturer of the irradiator and its safety systems. Hence, it is necessary for the irradiation facility to define procedures on working safely in the facility. Examples of conditions to be examined in the safety analysis report include:

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- Loss of access control;
- Malfunctions and failures of structures, systems and components;
- Loss of control over the source movement system1;
- Loss of system or component integrity, including shielding, sourceencapsulation1 and pool integrity1;
- Electrical distribution faults, from very localized faults to complete loss of external energy sources;
- Failure resulting from external causes such as storms, floods, earthquakes or explosions;
- Failure of personnel to observe proper, safe procedures (for whatever reasons);
- Breakdown of procedures for preventing access to the facility by unauthorized persons;
- Breakdown of administrative procedures, leading to unsafe practices.

4.2. Fixed radiation monitor with alarms

A monitoring system with built-in redundancy shall be provided to detect the radiation level in the radiation room when the irradiation is indicated to be terminated [8].The monitor shall be integrated with the personnel access door interlocks to prevent room access when the monitor detects a radiation level in excess of that specified, malfunctions or is turned off. The monitor shall generate visible and audible alarm signals if the radiation level exceeds that specified when the irradiation is indicated to be terminated. This is a potentially hazardous situation in which it may be necessary to override interlocks or other safety systems.

4.3. Programmable electronic requirements (revised in req. formate)

Programmable systems have become very important in all manner of process control applications in recent years. On one hand, programmable systems have many advantages such as flexibility and safety integrity to manufacturing and materials processing. On the other hand, there is a weakness in using programmable devices such as microprocessors and of software represented in predicting all the ways in which such systems could fail. Therefore, their use in safety-related control systems has to take account of this weakness [10]. As a general rule, the consequences to irradiator safety of erroneous programmable controller 'decisions' shall be addressed at the design stage. All possible failure modes shall be identified so that provision can be made to either mitigate their safety consequences or prevent their occurrence. Mitigation involves the use of redundancy in the function affected by a fault so that it continues to be provided; programmable controller and software replication are examples of this technique. Prevention shall involve the use of hazard analysis to determine the specification, design, testing and maintenance needed to ensure that software and hardware performance meet a specified level of safety integrity.

4.4. Qualified Operator Requirements

4.4.1. Training Program

A training program has to be prepared for different trainees. A training session for the radiation safety officers necessarily covers much more on basic physics, methods of measurements, regulatory requirements, than for a worker in the warehouse. The training shall cover at least the following topics [5]:

1- A knowledge of the basic design, operation and preventive maintenance of the irradiator;
2- An understanding of area security safeguards such as locks, posting of signs, warning lights, audible and visible signals, and interlock systems;
3- The principles and practices of radiation protection; the biological effects of radiation; the written procedures for routine and emergency irradiator operation;
4- A knowledge of the principal requirements of legislation, regulations and codes of practice as laid down by regulatory body and relevant to the operation of the irradiation facility;
5- Acknowledge of exposure rates at all areas around the irradiator and the radiation detection instrumentation which is used and the requirements for personal dose monitoring as specified by regulatory body.

At the minimum, the training program should strongly emphasize the following objectives and attitudes:

- Follow procedures if in doubt, ask the radiation safety officer.
- Treat all alarms as if they were severe, until proven otherwise.
- When entering the irradiation room, always use hand-held monitor and ensure its operation.
- Report all malfunctions to the radiation safety officer or the facility manager.

– Never bypass safety systems.

4.4.2. Qualified Operator

A qualified operator shall holds a certificate of passing the approved training. Each operator shall demonstrate competence to use the radiation source and its related components, and to maintain the required operation logs and records. Operators shall understand the overall organizational structure pertaining to management of the irradiator, including specific delegations of authority and responsibility for operation of the irradiator [6]. Only qualified operators shall be authorized to be responsible for the routine operation of the irradiator and shall ensure that the established safety procedures are observed. Qualified operators are those who work most closely with a particular irradiator and day-to-day responsibility for safe operation is generally theirs. The operators training, experience, attitude, safety culture and competence will establish the degree of safety associated with operation of the irradiator. Human factors such as operator error, deliberate acts to undermine safety systems and responses by people to incidents also need to be considered. Most irradiator incidents which have been reported world-wide have been caused, at least in part, by human factors and so it is vitally important that these issues are properly addressed.

4.5. Power Failure

Electrical safety control systems shall not be compromised in the event of a power failure. Means shall be provided to ensure that if an electrical power failure occurs, the source will automatically be returned to the fully shielded position and the irradiator shut down. Power failure is more related to the following [11]:

- If electrical power at a panoramic irradiator is lost for longer than ten seconds, the sources must automatically return to the shielded position.
- The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.
- During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.
- Determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources;

4.6. Door Interlock

- Personnel Access Door Interlocks Means shall be provided such that the personnel access door to the radiation room is closed and secured before the irradiation process can begin [6].
- The door interlocks shall be integrated with the master control system such that violation of the interlock system or use of the door will cause the radiation to be automatically terminated.
- Any failure of the control system shall generate visible and audible alarm signals.
- Opening the access door shall also disable the source hoist control circuit and cut off the motive power to the source hoist operating mechanism in the case of gamma facilities, or switch off the high voltage supply for electron beam facilities [11].
- The disabling of the source hoist control circuit and the cut-off of the motive power to the source hoist operating mechanism shall be accomplished by independent actions.
- The door shall not prevent any person in the radiation room from leaving. In addition, there should be an independent backup access control to detect the entry of personnel while the sources are exposed.
- Detection of entry while the sources are exposed shall cause the sources to return to their fully shielded position and shall also activate an alarm to warn the individual entering the room of the hazard.

4.7. Respond to Alarms

- The alarm shall also alert at least one other individual on site that entry has occurred. That individual shall have been trained on how to respond to the alarm and be prepared to promptly render or summon assistance [11].
- Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite whenever the irradiator is operated using an automatic product conveyor system and whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

4.8. Entering Radiation Room [12]

a. Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.
b. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

- Visually inspect the entire radiation room to verify that no one else is in it; and
- Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

4.9. Product Entry and Exit [13]

- Product Entry and Exit Port Interlocks Suitable means shall be provided at the product entry and exit ports to prevent inadvertent entry of personnel into high radiation areas.
- The ports shall be inter-locked such that a visible or audible alarm indicates when the entry/exit port control mechanism has malfunctioned or has been overridden or tampered with.
- The irradiation shall be automatically terminated when this occurs and shall prevent the irradiation from being restarted unless the cause has been remedied [5].
- To ensure that the interlock cannot be tampered with, the interlocked control shall not be accessible outside the radiation shields.

4.10. Radiation Monitor [6], [8]

- A monitoring system with built-in redundancy shall be provided to detect radiation levels in the irradiation room.
- The monitor shall be integrated with the personnel access door interlocks to prevent room access when the monitor detects a radiation level in excess of that specified, or when it malfunctions or is turned off.
- The monitor shall generate visible and audible alarm signals if the radiation level exceeds that specified when the irradiation is indicated to be terminated.
- The pre-set alarm must be set sufficiently above the natural background level to avoid excessive number of false alarms.

4.11. Control System

Each irradiator shall have a master control console that shall be used to prevent unauthorized operation.Means shall be provided to terminate irradiation and turn the irradiator off at any time. Access key control systems shall be designed to ensure that there can be no more than one access key in use at any given time, e.g. the irradiator controls may be designed such that a single multipurpose key is used to operate the irradiator during normal use. This key may be used to operate the control console, gain access to the radiation room and to actuate the safety delay timer. In systems employing two or more keys, one key must remain captive (trapped within the lock) when the other keys are being used [6], [7].

4.12. Emergency Requirements

- Emergency Stop Device Emergency Stop Device Means shall be provided within the radiation room to prevent, quickly interrupt or abort irradiator operation and terminate irradiation at any time. A clearly labeled emergency stop device shall be provided at the control console to prevent, quickly interrupt or abort irradiator operations and terminate irradiation at any time.The device shall be clearly labeled and readily accessible to workers in the radiation room, and shall cause visible or audible signal to be given outside the room [6], [7], [8].

- Emergency exit or shielding For the protection of anyone inadvertently shut inside the radiation room one or more of the following systems shall be provided:

    - A means of exit from the radiation room. This may require a system for opening the personnel access door from inside the radiation room, thus activating the normal safety interlocks; and
    - A clearly marked location where radiation dose rates are sufficiently low.

4.13. Control of Source Movement

- The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key [12].
- The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed [13].
- The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.
- Each control for a panoramic irradiator must be clearly marked as to its function.

4.14. Operating and emergency procedures.

(A) The licensee shall have and follow written operating procedures for [12]:

- Operation of the irradiator, including entering and leaving the radiation room;
- Use of personnel dosimeters;
- Surveying the shielding of panoramic irradiators;
- Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
- Leak testing of sources;
- Inspection and maintenance checks.
- Loading, unloading, and repositioning sources, if the operations will be performed by the licensee.

(B) The licensee shall have and follow emergency or abnormal event procedures for [12]:

- Sources stuck in the unshielded position;
- Personnel overexposures;
- A radiation alarm from the product exit portal monitor or pool monitor;
- Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
- A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;
- A prolonged loss of electrical power;
- A fire alarm or explosion in the radiation room;
- An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;
- Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and
- The jamming of automatic conveyor systems.

4.15. Inspection and maintenance

(A) The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application [13]:

- Operability of each aspect of the access control system.
- Functioning of the source position indicator.
- Operability of the radiation monitor for radioactive contamination in pool water.
- Operability of the over-pool radiation monitor at underwater irradiators.
- Operability of the product exit monitor required.
- Operability of the emergency source return control.
- A visual inspection of the leak-tightness of systems through which pool water circulates.
- Without turning extinguishers on, operability of the heat and smoke detectors and extinguisher system.
- Operability of the means of pool water replenishment.
- Operability of the indicators of high and low pool water levels
- Operability of the intrusion alarm
- Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.
- Condition of the barrier to prevent products from hitting the sources or source mechanism.

- Amount of water added to the pool to determine if the pool is leaking.
- Electrical wiring on required safety systems for radiation damage.
- Pool water conductivity measurements and analysis.

(B) Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

4.16. Recording and Reporting requirements

Keeping records of near-miss events is a good practice so that the circumstances which led to them can be avoided. Also, operational records can be used in the analysis of plant performance and help to reveal trends which could lead to an incident. When records of plant performance or safety indicate that changes to operational procedures or plant design are needed, the employer should ensure that both the hazard assessment and contingency plan are updated accordingly. Examples of incidents which should be recorded and which would require immediate investigation are [13]:

- Source stuck in an unshielded position.
- Any fire or explosion in a radiation room.
- Damage to the source racks.
- Failure of the cable or drive mechanism used to move the source racks.
- Inoperability of the access control system.
- Detection of radiation source by the product exit monitor.
- Detection of radioactive contamination attributable to licensed radioactive material.
- Structural damage to the pool liner or walls.
- Abnormal water loss or leakage from the source storage pool.
- Pool water conductivity exceeding one hundred micro siemens per centimeter.

Conclusions

As the target of radiation safety is to protect human and environment from radiation hazards, Special design and operation precautions are taken to avoid the exposure to gamma radiation which is continuously emitted by the radiation source. Safety could not be achieved by only good and verified design but also by regulated operation and maintenance. To this end, this paper focuses on the operation and maintenance requirements that grantee accidents free operation, which could result from human errors, or other systems failure or malfunction. This paper proposes sixteen regulatory requirements for operation and maintenance of gamma irradiator. These requirements represent the most important ones which are agreed upon by different international regulatory bodies.

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