ABSTRACT

Regulatory inspections are one of the most important elements of a regulatory programme. It shall be performed in all areas of the regulatory responsibility and during all phases of siting, design, construction, commissioning, operation, maintenance and decommissioning of an irradiator facility.

The Egyptian Mega Gamma irradiator operating since December 1979 has a Co-60 source of about 400 kiloCuries and is used mainly for sterilization of medical supplies and pharmaceuticals and for preservation of some food stuffs. The constructor (Nordion International Inc.) recommended an extensive inspection programme. In accordance with the International (1) and National (2,3) regulations as well as the licensing conditions, the competent authority (NCNSRC) shall perform regulatory inspections both announced and unannounced.

In order to facilitate the inspection task and to harmonize the inspection reports a checklist for inspection is proposed which can be used also as an inspection report form.

Key Words: Regulatory Inspection, Category IV Gamma Irradiator, Inspection Checklist.

1- INTRODUCTION

The Egyptian Mega gamma irradiator is a category IV wet pool gamma irradiator constructed by Nordion International Inc. type J.S.6500. The radioactive source is Co-60 cylindrical rods doubly encapsulated in 316 L stainless steel (pencils) which are assembled onto a source rack. The radiation source is lowered by remote control in a water filled storage pool where the source is fully shielded when not in use. When the source is in exposed position the irradiation room is maintained inaccessible by entry control system.

The principal objectives of regulatory inspections are to ensure that:

- All specifications, codes and practices proposed by the licensee and accepted by the competent authority are complied with.
- The quality and performance of components, structures and systems required by the competent authority are achieved and maintained by the licensee.
- Any deficiencies in equipment and procedures are corrected by the licensee without undue delay.
• The licensee is fulfilling the requirements and conditions set out in the pertinent regulations and in the approval.
• The approved operation procedures are being followed.
• The personnel are competent to operate the facility safely.

In addition to the normal regulatory inspection activities, the competent authority shall carry out regulatory inspections if an abnormal occurrence requires immediate investigations.

2- Constructor inspection programme.

The constructor (Nordion International Inc.) recommended a periodic inspection programme which comprises:

2-1 Weekly inspections

The weekly inspection includes
• Radiation levels at air filter bank and water deionizer and pumps.
• Water treatment plant equipment and water parameters.
• Chiller operating parameters.
• Warning lights and alarms.
• Control console equipment and functions.

2-2 Monthly inspections

Every month the following items shall be checked
• Irradiation stop controls.
• Source hoist and guide cables
• Radiation survey at selected positions (storage position).
• Radiation monitors and personnel door interlock.
• Ventilation system.
• Automatic shut down devices.
• Cylinders, carriers, load / unload elevators, cross transfer and loggers.
• Overdose control.
• Radiation detection instruments.

2-3 Quarterly, Semi-annual and Annual inspections

The electrical relays, power interruption and nylon rollers are checked quarterly.

Leak tests on source rack and recalibration of survey meters are verified semi-annually.

Cylinder packing and microswitches in the source pass and interim areas are replaced annually.

3- Checklist for routine regulatory inspection

3-1 General information

Date of visit
Visit to
Facility inspected
Purpose of Inspection

1051
Inspector's name(s) Accompanied by Persons met
Accompanied by
Persons met

3-2 Before visit

Make arrangements with operator (unless visit is to be un-announced)
Confirm if access to cell is required (disruption of production etc)
Confirm if particular persons must be present at inspection
Arrange for personal dosimeters for inspectors
Arrange for hand held radiation survey meter for inspectors (DO NOT RELY ON OPERATOR)
Prepare/modify checklist to suit purpose of visit and individual facility
Make list of other matters to be discussed
Review reports of previous visits and identify any recommendations not yet implemented

3-3 Immediately prior to visit

Check personal dosimeters
Check operation of hand held radiation survey meters

3-4 Initial discussions with the operator

Explain scope of inspection (i.e. what aspects are to be inspected)
Have there been any personnel changes?
  • New management?
  • New qualified experts?
  • New Radiation Protection Officer?
  • New operators?
What training has been given for new personnel
Have there been any modifications to the irradiator since previous inspection (including source changing)
Have there been any incidents / accidents / problems
  • Source stuck
  • Pool water problems
  • Interlock failures
  • Failures to comply with procedures
  • Unusual results on personal dosimeters
  • Need to over-ride interlocks?
What is the relationship with the irradiator manufacturer/source supplier
  • Is it still on-going?
  • Does the supplier do preventative maintenance and inspections?

3-5 RECORDS

Radiation safety instructions (local rules)
  • Still available to all those who need them?
  • Up to date?
  • Any changes? (get copy of new version)
Records of training of operators
Records of authorization of operators
Confirms there is a continuous record of plant modifications and that it is up to date
Ask to see manufacturers/suppliers inspection reports
Confirms that there is an irradiator log-book completed daily and that it is up to date
Ask to see radiation dosimeter results -- any unusual doses?
Ask to see test/calibration certificate for hand held radiation survey meters.
Inspect records of operators own safety checks.
Confirm they include
- Radiation dose rate surveys
- Radiation detectors inside the irradiator
- Product exit point monitors
- Pool water treatment equipment monitor
- Analysis/frequency of pool water samples
- Emergency cut off switched (inside and outside)
- Heat and/or smoke sensors
- Inspection of components inside the irradiator room (for radiation damage)
- Warning lights and signals (inside, outside and on control panel)

3-6 Physical inspection of irradiator

General

- is the building tidy
- is the building secure

Attitude or operators

It is useful to question the operators to assess their knowledge of radiation protection and irradiator operating procedures.

- Do they pay attention to control panel indicators and other warning signals?
- Are they wearing their personal dosimeters and other devices, e.g. quartz-fibre Electrometer / personal alarm monitor
- Do they check the irradiator status warning signal positioned at the access door?
- Do they test the hand held survey meter using the fixed check source before entering the irradiator room
- Do they actually use the hand held survey meter as they enter the room?
- When they leave the irradiator room do they check carefully to see there are no persons inside

Outside the Irradiator

Are fixed warning notices present?
Are all automatic warning signals operating?
- At personal access door
- At product entry/exit points
- On control panel
Are product carriers in good condition?
Any changes to the lay-out or shielding?
Check dose rates

REFERENCES

1- IAEA, Radiation Safety of Gamma and Electron Irradiation Facilities, Safety Series No 107, IAEA, Vienna, 1992
