

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03019882/2011001
Docket No. 03019882
License No. 52-21175-01
Licensee: Baxter Healthcare of Puerto Rico
Location: Road 721, km. 0.3
Aibonito, PR 00705
Inspection Dates: December 13, 2011

Inspector: /RA/ 1/3/2012
Michael Reichard
Health Physicist
Materials Security and Industrial Branch
Division of Nuclear Materials Safety
date

Approved By: /RA/ 1/3/2012
Blake D. Welling, Chief
Materials Security and Industrial Branch
Division of Nuclear Materials Safety
date

EXECUTIVE SUMMARY

Baxter Healthcare of Puerto Rico
NRC Inspection Report No. 03019882/2011001

This announced safety inspection at the Baxter Healthcare of Puerto Rico (Baxter) Aibonito facility on December 13, 2011, was conducted to examine Baxter's licensed activities related to its irradiator radiation safety program. Based on a review of Baxter's activities, the inspector verified that Baxter had implemented a program to ensure that radiation safety operations were being performed appropriately and in compliance with applicable requirements. The inspection was performed in accordance with Inspection Procedure (IP) 87122, Irradiator Programs.

No violations were identified.

REPORT DETAILS

I. Organization and Scope of the Program

a. **Inspection Scope** (IP 87122, FE-7)

The inspector reviewed the licensee's organization and scope of activities related to its gamma sterilization department. [10 CFR 36.65]

b. **Observations and Findings**

Baxter operates a manufacturing and distribution facility for single-use medical equipment. The medical equipment is sterilized prior to distribution, using an MDS Nordion irradiator containing cobalt-60 sealed sources. The last resourcing occurred in October 2010. The irradiator facility operates 24 hours per day, seven days per week, excluding holidays.

The licensee has five trained operators, one for each of the five shifts. The program is directly overseen by the Radiation Safety Officer, who directly reports to the Plant General Manager.

c. **Conclusions**

The inspector determined that the licensee's organization for the gamma sterilization department was fully staffed and provided adequate oversight and control of the radiation safety program. No violations were identified.

II. Training of Workers

a. **Inspection Scope** (IP 87122, FE-6)

The inspector reviewed the licensee's training program including training materials, class attendance logs, examinations, and emergency drill documentation. [10 CFR 19.12, 10 CFR 36.51, and 10 CFR 36.81]

b. **Observations and Findings**

The inspector reviewed the licensee's training materials and determined that the required subject matter was appropriately covered. The inspector verified that irradiator management, irradiator operators, and other gamma sterilization workers were appropriately trained and tested for their levels of responsibility.

c. **Conclusions**

The inspector determined that Baxter's training program was in compliance with applicable requirements. The inspector also determined that all applicable irradiator facility workers were appropriately trained commensurate with their areas of responsibility. No violations were identified.

III. Sealed Source Accountability Program

a. Inspection Scope (IP 87122, FE-1)

The inspector reviewed the licensee's sealed source accountability program including a review of the licensee's inventory and transfer documentation. [10 CFR 30.51]

b. Observations and Findings

The inspector reviewed the licensee's sealed source accountability program and determined that the licensee was able to track and reconcile their inventory through both inventory records and transfer records.

c. Conclusions

The licensee was able to account for all radioactive material. No violations were identified.

IV. Radiation Surveys

a. Inspection Scope (IP 87122, FE-2 and FE-5)

The inspector reviewed the licensee's radiation survey program including the licensee's use of hand held survey instruments, area radiation monitors, and examining calibration records for radiation detection equipment. [10 CFR 36.29 and 10 CFR 36.57]

b. Observations and Findings

The inspector observed the use of survey instruments and electronic dosimeters in the irradiator vault while the sources were in the shielded position. The inspector determined that the licensee used the equipment in compliance with applicable requirements and Baxter's procedures. The inspector observed audible and visual alarms as the irradiator resumed operation.

The inspector performed independent radiation surveys outside of the irradiator vault during irradiator operations, including on the roof of the facility. The inspector also performed surveys in the irradiator vault when the sources were in the shielded position. All radiation measurements were below applicable regulatory limits.

The inspector reviewed Baxter's calibration certificates for its various radiation detection equipment including hand held survey instruments, electronic dosimeters, and area monitors. The inspector determined that the equipment was routinely calibrated in compliance with applicable requirements.

c. Conclusions

The inspector determined that the radiation safety equipment was appropriately maintained, calibrated, and used in compliance with applicable regulations and licensee procedures. The inspector determined that radiation levels in accessible areas were below applicable limits. No violations were identified.

V. Pool Water Monitoring

a. Inspection Scope (IP 87122, FE-1)

The inspector reviewed the licensee's pool water monitoring program, including pool sediment monitoring. The inspector reviewed applicable contamination monitoring records. The inspector also reviewed Baxter's sewer release program. [10 CFR 36.59 and 10 CFR 36.63]

b. Observations and Findings

The inspector observed that Baxter continuously monitors irradiator pool water for radioactive contamination as it is circulated through a filtration system. The licensee also measures for contamination on the water filters when they are changed.

When the irradiator has a resourcing outage, the licensee cleans out sediment from the pool. The sediment is monitored for contamination prior to disposal.

Also during resourcing outages, when the sealed source transportation container is lowered into the irradiator pool, water flows into an overflow tank. After the resourcing has been completed, the overflow tank water is monitored for contamination prior to release to the sewer.

c. Conclusions

The inspector determined that the licensee has implemented an appropriate pool water monitoring program in compliance with applicable regulatory requirements and Baxter's procedures. A review of the applicable records determined that no leaking sources have ever been identified. No violations were identified.

VI. Personnel and Public Exposure Monitoring

a. Inspection Scope (IP 87122, FE-1 and FE-4)

The inspector reviewed the licensee's personnel and area dosimetry program. [10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.1501, 10 CFR 20.2106, and 10 CFR 36.55]

b. Observations and Findings

The inspector observed staff appropriately wearing their personnel dosimetry. The licensee monitors exposures to members of the public by placing area dosimeters around the irradiator facility to ensure that radiation doses are within regulatory limits. The inspector reviewed the personnel and area dosimetry results.

c. Conclusions

The inspector determined that exposures to irradiator staff and members of the public were below the allowable limits. No violations were identified.

VII. Postings

a. Inspection Scope (IP 87122, FE-1 and FE-6)

The inspector reviewed the licensee's postings. [10 CFR 19.11, 10 CFR 20.1902, 10 CFR 20.1904, 10 CFR 21.6, and 10 CFR 36.23]

b. Observations and Findings

The inspector observed appropriate postings at each entrance into the irradiator facility. Very High Radiation Area postings appropriately illuminated when the irradiator was in operation. Required informational notices were posted in the irradiator area as well as common areas.

c. Conclusions

The inspector determined that the licensee was in compliance with applicable posting requirements. No violations were identified.

VIII. Program Oversight

a. Inspection Scope (IP 87122, FE-3)

The inspector reviewed Baxter's annual audits and management oversight. [10 CFR 20.1101 and 10 CFR 20.2102]

b. Observations and Findings

The Radiation Safety Officer directly oversees all aspects of the radiation safety program. The Radiation Safety Officer performs a detailed audit of the radiation safety program each year. The inspector reviewed the annual audits for the past two years.

c. Conclusions

The inspector determined that the annual audits were thorough and timely. Neither audit identified any violations or safety concerns.

The inspector determined that the Radiation Safety Officer was aware of and implementing applicable radiation safety requirements. The inspector determined that the Radiation Safety Officer receives appropriate support from Baxter management to maintain a radiation safety program in compliance with NRC requirements. No violations were identified.

IX. Exit Meeting

An exit meeting was conducted on December 13, 2011, by the inspector with the Radiation Safety Officer and Baxter management representatives.

PARTIAL LIST OF PERSONS CONTACTED

#* Jose Arroyo, Radiation Safety Officer
#* Luis Lora, Engineering Director
#* Margarita Cruz Casse, Director of Manufacturing

Individuals present at entrance meeting
* Individuals present at exit meeting