

U. S. NUCLEAR REGULATORY COMMISSION

REGION II

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License No.: 52-21175-01

Report No.: 52-21175-01/97-01

Licensee: Baxter Healthcare Corporation

Location: Aibonito, Puerto Rico

Dates: April 2, 1997

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EXECUTIVE SUMMARY

Baxter Healthcare Corporation NRC Inspection Report 52-21175-01/97-01

This special, unannounced inspection was conducted to evaluate Baxter Healthcare Corporation's (BHC) radiation safety program for operation of its pool irradiator and to review licensee compliance with license condition 14. Through discussions with licensee staff, reviews of documents, and observations of equipment, instrumentation, and the operation of the irradiator by licensee staff, the inspectors found the overall radiation safety program to be adequate; however, three apparent violations were identified including: (1) multiple examples of apparent violations of license condition 14, (2) an apparent violation of 10 CFR 36.63(b) concerning pool water quality, and (3) an apparent violation of 10 CFR 36.51(e) concerning annual operator audits. Program areas included in this report were management oversight, organization and scope of the program, training, retraining, and instructions to workers, operating and emergency procedures, facilities, equipment and instrumentation, operations, inspection and maintenance, materials receipt, use, transfer, and control, area radiation surveys and contamination control, personnel radiation protection, and posting and labeling.

Management Oversight

- BHC management structure and staff remains as found during the last inspection.
- The inspectors identified an apparent violation relating to the licensee's failure to conduct annual safety audits of irradiator operators in 1996. (Section 1.0)

Organization and Scope of the Licensee Program

- BHC is authorized to possess and use up to 5,000,000 curies of cobalt 60 in their Nordion Model IR130 wet storage irradiator.
- NRC License No. 52-21175-01 authorizes the irradiation of materials, other than those of an explosive or hazardous nature, or food for human consumption.
- The licensee conducts a 24 hour/day operation at the plant.

Training, Retraining, and Instructions to Workers

- BHC irradiator operators and other personnel were found to be trained in BHC's radiation safety program.
- BHC's workers received instructions commensurate with their participation in activities involving the use of licensed materials.

Operating and Emergency Procedures

- BHC operating and emergency procedures were found to be established, maintained and implemented.

- The inspectors identified that the licensee toured and trained the local police and fire departments and medical emergency responders on BHC emergency response procedures.

Facilities, Equipment and Instrumentation

- BHC's facilities were found to be as described in its license application.
- Safety-related equipment and instrumentation was found to be properly maintained, calibrated and in working order, with one exception discussed below.
- The inspectors identified an apparent violation in that the pool water conductivity meter was found not calibrated. (Section 5.0)

Operations

- BHC's systems designed to control source movement were found to be as described in its license application and were properly maintained and in working order.
- Operators were found to be qualified in accordance with regulatory and license requirements.

Inspection and Maintenance

- The licensee performed inspection checks of systems and safety related equipment in the manner and at the frequency described in its license application.
- The inspectors identified an apparent violation in that the licensee conducted unauthorized maintenance of safety systems on the irradiator. (Section 7.0)

Materials Receipt, Use, Transfer, and Control

- The inspectors determined that the licensee received, surveyed, secured, used and controlled all possessed licensed material in accordance with NRC requirements.

Area Radiation Surveys and Contamination Control

- The licensee performed ambient radiation dose rate surveys and contamination surveys as required.
- Surveys conducted by the licensee indicated that the dose rates in and around the irradiator facility were maintained as low as reasonably achievable (ALARA) and that cobalt 60 sources had not leaked.

Personnel Radiation Protection

- Licensee personnel dosimetry records demonstrated that personnel exposures were routinely below the minimum detectable levels of the dosimeters and that personnel exposures were ALARA.

Posting and Labeling

- The licensee had posted all required notices and warning signs.

LIST OF PERSONS CONTACTED

Licensee

- #E. Betancourt, Plant Manager
- *L. Alvarado, Operations Manager
- *J. Rivera, Sterilization Superintendent
- *O. Camacho, Radiation Safety Officer
- *A. Alicea, Engineer/Alternate Radiation Safety Officer

*Present at outbrief on April 1, 1997

#Contacted by telephone on April 15, 1997

REPORT DETAILS

01. Management Oversight (87100)

a. Inspection Scope

The inspectors reviewed the licensee's organization and management oversight to determine whether the organization and staffing were as required by the license, and whether reviews and audits by licensee management were in accordance with license requirements.

b. Observations and Findings

Through discussions with cognizant licensee representatives, the inspectors were able to determine that, as authorized in the license, the RSO reports to the Plant Superintendent, who reports to the Operations Manager, who then reports to the Plant Manager. While reviewing the records of training, and weekly/monthly safety checks of the irradiator safety systems, the inspectors were able to determine that either the RSO or ARSOs reviews and signs training and safety check records. By reviewing the personnel dosimetry records, the inspectors were able to determine that the RSO also reviews the personnel dosimetry records on a monthly basis. Based upon discussions with licensee personnel and review of records, the inspectors determined that the RSO and ARSO are involved in the radiation protection program. 10 CFR 36.51(e) requires, in part, that the licensee evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. While conducting interviews with licensee staff, the inspectors determined that the licensee failed to conduct irradiator operator annual evaluations, for the year 1996. The licensee's failure to evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures were followed was identified as an apparent violation of 10 CFR 36.51(e).

c. Conclusions

As evidenced by the findings in this report, and the trend set since the previous inspection, it appears the effectiveness of licensee's management oversight has declined as indicated by the failure to evaluate the safety performance of each operator in 1996.

02. Organization and Scope of the Licensee Program (87100)

a. Scope

The inspectors reviewed the licensee's activities to determine whether the quantities of materials possessed and activities were as authorized in the license.

NRC License No. 52-21175-01 authorizes BHC to possess up to 5,000,000 curies of cobalt 60 for possession and use in a Nordion Model IR130 wet storage custom irradiator for irradiation of materials, excluding those of an explosive or hazardous nature, or food for human consumption. The licensee staff should consist of one RSO, two ARSOs (also qualified as operators), three trained operators and one alarm responder. The licensee is authorized to operate a 24 hour, 7 days a week operation.

b. Observations and Findings

While conducting the inspection, the inspectors observed that the irradiator was being used to irradiate medical products. While touring the facilities, the inspectors noted that to avoid a backlog of non-sterile product, the licensee keeps a full time operation.

c. Conclusions

The inspectors found that the licensee's irradiator contained an amount of licensed material within the limits specified in the license and that materials being irradiated were as authorized by the license.

03. Training, Retraining, and Instructions to Workers (87100)

a. Scope

The inspectors reviewed the training records of all operators and alarm responders, and maintenance staff to determine whether they met the requirements of 10 CFR 19.12, 10 CFR 36.51 and the license.

b. Observations and Findings

The inspectors determined that irradiator operators and alarm responders received annual training on irradiator operations and emergency procedures in 1996. While conducting direct observations of the licensee staff during the operation of the irradiator and review of the records, the inspectors determined that the licensee staff was knowledgeable of the safety requirements associated with their job duties, and that the licensee had established and implemented an adequate training, retraining and instructions to workers program. The inspectors determined that the licensee had corrected the apparent violation identified in NRC Inspection Report No. 52-21175-01/ 96-02 regarding radiation safety training of maintenance staff commensurate with their involvement in licensed activities.

c. Conclusions

The inspectors found that the licensee had implemented an adequate training, retraining, and instructions to workers program.

04. Operating and Emergency procedures (87100, 83822)a. Scope

The inspectors reviewed the licensee's operating and emergency procedures to determine whether they are adequately available to operators, and whether operators were adequately trained.

b. Observations and Findings

The inspectors reviewed the licensee's operating and emergency procedures which were maintained in the irradiator control room. The inspectors reviewed the licensee's operational data logbook. The inspector reviewed the licensee's training records regarding emergency procedures training/retraining. The inspectors found that all operators were adequately trained in the operating and emergency procedures.

The inspectors found that these procedures included the required topics for both routine operations and emergency conditions and that the procedures appeared adequate for their intended purpose. The inspectors found that the operational data logbook maintained by the licensee contained the required information regarding source movements and operational problems. The inspector determined that the local police, firefighters and medical emergency responders were trained in the licensee's emergency procedures and had toured the licensee's facility.

c. Conclusions

The licensee had effectively implemented adequate operating and emergency procedures as required. The licensee had effectively trained irradiator operators in BHC's operating and emergency procedures.

05. Facilities, Equipment and Instrumentation (87100, 83822)a. Scope

The inspectors reviewed the operability and calibration of the licensee's facility, equipment and instrumentation to determine whether they met the requirements 10 CFR Part 36 and the license.

b. Observations and Findings

The inspectors toured the facility and found that it was as described in the license application. The inspectors found that access controls, barriers, radiation monitors, heat and smoke detectors, fire extinguishing systems and source rack protection devices were in place, maintained as required and operational. The

inspectors observed that the licensee possessed appropriate radiation survey instruments which were calibrated on an annual basis.

The inspectors reviewed the calibration records for the portable survey instruments, fixed radiation monitors, and laboratory instruments used to analyze contamination smears since the last inspection and also tested the performance of some of the instruments during the inspection. The inspectors examined the licensee's water cleanup and cooling system. The licensee used demineralizers to maintain pool clarity and used radiation monitors to detect contamination in the water circulating through the system. 10 CFR 36.63(b) requires, in part, that the licensee measure the pool water conductivity with a conductivity meter calibrated at least annually. The inspectors determined that the licensee had never calibrated the conductivity meter since its installation. Licensee staff indicated that the instrument was non-removable from the pipe system and that for that reason, it had never been taken out to the lab for calibration. The inspectors confirmed that the conductivity meter detectors were non-removable as indicated by the licensee, and that they had been in place and uncalibrated for several years. The licensee's failure to measure pool water conductivity with a conductivity meter calibrated at least annually was identified as an apparent violation of 10 CFR 36.63(b).

c. Conclusions

The licensee's facility, equipment and instrumentation were adequate with the exception that the pool water conductivity monitor was not calibrated as required.

06. Operations (87100, 83822)

a. Scope

The inspectors observed the licensee staff operate the irradiator to determine whether it was being operated as required by the license.

b. Observations and Findings

The inspectors found that the licensee staff who operate the irradiator were knowledgeable in irradiator operations and qualified as required. The inspectors found that required operational controls (such as the requirement that the same key that operates the irradiator must be used to enter the irradiation room, interlock systems on personnel entry doors, source position indicators on the control console, and visible and audible alarms) were utilized and operable. The inspectors observed the irradiator operators entering the irradiation room and found that the operators did so in accordance with appropriate procedures.

c. Conclusions

Operations conducted by the licensee as observed by the inspectors were in compliance with regulatory and license requirements.

07. Inspection and Maintenance (87100, 83822)

a. Scope

The inspectors reviewed the licensee's inspection and maintenance activities to determine whether they were in accordance with license requirements.

b. Observations and Findings

The inspectors observed licensee staff perform the weekly safety and maintenance checks of the irradiator and its safety related systems. The inspectors also reviewed the records of the weekly and monthly safety and maintenance checks performed since the last inspection on May 15, 1996.

Condition 14 of NRC License No. 52-21175-01, requires, in part, that the licensee not perform repairs and/or alterations on the irradiator, its control console and safety systems, its shielding or any other mechanism that might affect the containment integrity of the sealed irradiator sources, the irradiator "on-off" mechanism or the physical security of the irradiation room. NRC Inspection Report No. 52-21175-01/96-02 identified licensee's apparent violation of license condition 14 (inspection conducted on October 29, 1996).

On October 31, 1996, the NRC issued a Confirmatory Action Letter (CAL) to the licensee requiring the licensee to retrain the staff in the limitations on repairs and/or alterations to safety systems as specified in license condition 14, and the requirement that such work be done by the irradiator manufacturer or other persons specifically licensed by the Commission or an Agreement State to do such work, or the licensee must obtain specific authorization in writing from the Commission before performing such work itself. On November 19, 1996, the licensee replied to the NRC's CAL and indicated that all irradiator operators and support personnel were retrained in a classroom environment on radiation safety at the irradiator facilities, and that limitations on repairs and/or alterations to safety systems as specified in license condition 14 was a part of this retraining.

While reviewing the maintenance log, the inspectors found that the licensee performed unauthorized repairs on four occasions (listed below). The inspectors found that on November 19 and 25, 1996, the licensee replaced the control console start switch, which is a key element to the "on-off" mechanism. The inspectors found that on March 10, 1997, the licensee repaired wiring from the DL2 No. 5 radiation monitor to the control console, an obvious component of the safety system. The inspectors found that on March 14, 1997, the licensee replaced a floor mat located in the product entrance area. This floor mat was a

key element of the personnel barrier system, a safety system which was used to detect personnel entry into the irradiator cell when sources were exposed, causing the loss of air pressure to the source rack hoist mechanism.

The inspectors found that the licensee performed checks of the safety interlocks/systems affected by the repairs immediately after completing the repairs; all systems were found operational during these post-repair tests.

On April 15, 1997, the inspectors contacted the licensee's Plant Manager by telephone. The purpose of the telephone conversation was to obtain BHC's understanding of license condition 14 in NRC License No. 52-21175-01. The licensee wrote a letter, dated April 15, 1997, which set forth BHC's understanding. The inspectors found that the April 15 letter from BHC stated a clear and accurate understanding of license condition 14 to NRC License No. 52-21175-01.

Licensee's repairs to the irradiator control console and safety systems, and other mechanisms that might affect the irradiator "on-off" mechanism or safety systems were identified as multiple examples of an apparent violation of NRC License No. 52-21175-01, Condition 14.

c. Conclusions

The licensee inspection and maintenance program were found to have deficiencies in that the licensee continued to perform unauthorized repairs to the control console and safety systems contrary to license requirements. These activities continued to occur after the October 29, 1996, inspection which identified these as violations. Post-repairs testing of the safety systems found they operated properly.

08. Materials Receipt, Use, Transfer, and Control (87100)

a. Scope

The inspectors reviewed the licensee's recent transfer and control of cobalt-60 to determine whether the transfer met requirements.

b. Observations and Findings

The inspectors reviewed materials receipt and transfer records. The inspectors interviewed licensee personnel. The inspectors conducted direct observations while conducting the inspection.

The inspectors found that the licensee recently received cobalt-60 sources to replenish the source racks. The inspectors found that in January 1997, the licensee increased its cobalt-60 possession from 3,821,599 curies to 4,479,220 curies.

The inspectors found that the trucks containing licensed material were parked in a secured area, surveyed according to NRC requirements, and opened in the presence of the irradiator/source manufacturer. The inspectors also found that unloading, installation and removal of decayed sources were all performed by the irradiator/source manufacturer.

c. Conclusions

The licensee properly received, controlled, used, and transferred licensed material.

09. Area Radiation Surveys and Contamination Control (83822)

The inspectors reviewed the licensee's survey program to determine whether it met the requirements of 10 CFR 20, 10 CFR 36, and the license.

a. Scope

b. Observations and Findings

The inspectors reviewed the records of area radiation surveys and contamination surveys that the licensee had performed since the last inspection.

The inspectors found that the licensee had used the appropriate survey instruments to perform surveys and that surveys were performed in the manner and at the frequency described in the license application and as required by regulations. The results of surveys revealed that dose rates in and around the irradiation room were ALARA and that the licensee had not detected any contamination in its facility.

c. Conclusions

Radiation dose rates in and around the licensee's facility were in compliance with NRC regulatory and license requirements. There is no contamination at the licensee's facility.

10. Personnel Radiation Protection (83822)

a. Scope

The inspectors reviewed the licensee's program for monitoring workers' doses to determine whether it met the requirements of 10 CFR 20, 10 CFR 36, and the license.

b. Observations and Findings

The inspectors observed licensee employees operating the irradiator. The inspectors reviewed the licensee's personnel dosimetry records for the period from May, 1996 to March, 1997.

The inspectors found that the licensee staff were wearing the appropriate personnel dosimeters.

c. Conclusions

Personnel exposures were routinely below the minimum detectable levels of the dosimeters and exposures were ALARA.

11. Posting and Labeling (87100, 83822)

a. Scope

The inspectors reviewed the licensee's program for posting of warning signs and notices to workers to determine whether they met the requirements of 10 CFR 19 and 20.

b. Observations and Findings

The inspectors performed direct observations while touring the facility. The inspectors observed that the licensee had posted NRC Form 3, "Notice to Workers" and that other required documents and warning signs were properly posted.

c. Conclusions

The licensee adequately posted and labeled all required areas.

EXIT MEETING SUMMARY

An exit meeting was held with licensee representatives on April 2, 1997. The overall findings from the inspection, including the apparent violations were discussed. In addition, the inspectors reiterated to licensee management, that in order to conduct some repairs on the irradiator safety systems, a license amendment requesting authorization to make repairs needed to be filed with the NRC for review and approval. No dissenting comments were received from the licensee, and the licensee did not specify any information reviewed during the inspection as proprietary in nature.

INSPECTION PROCEDURES USED

IP 87100 Licensed Materials Program
IP 83822 Radiation Protection

ITEMS OPENED, CLOSED, AND DISCUSSED

OPENED

97-001	VIO	UNAUTHORIZED MAINTENANCE OF SAFETY SYSTEMS
97-002	VIO	FAILURE TO CALIBRATE CONDUCTIVITY METER
97-003	VIO	FAILURE TO CONDUCT OPERATORS ANNUAL AUDITS

CLOSED

96-001	FAILURE TO TRAIN PERSONNEL
96-002	FAILURE TO HAVE ROOF PLUG INTERLOCK
96-004	FAILURE TO MAINTAIN RECORDS OF REPAIRS

DISCUSSED

None.