

RI - DNMS Licensee Event Report Disposition

Licensee:	Baxter Healthcare of Puerto Rico - Aibonito Plant			
Event Description:	Irradiator Pool Water Conductivity Exceeds Limits			
License No:	52-2117501	Docket No:	0301982	MLER-RI: 2019-003
Event Date:	01/21/19	Report Date:	01/22/19	HQ Ops Event #: 53839

1. REPORTING REQUIREMENT

<input type="checkbox"/> 10 CFR 20.1906 Package Contamination <input type="checkbox"/> 10 CFR 20.2201 Theft or Loss <input type="checkbox"/> 10 CFR 20.2203 30 Day Report <input checked="" type="checkbox"/> Other 10 CFR 20.36.83 ^{MIX} 10 CFR 36.83 (a)(10)	<div style="text-align: right; margin-bottom: 10px;">NMED 190040</div> <input type="checkbox"/> 10 CFR 30.50 Report <input type="checkbox"/> 10 CFR 35.3045 Medical Event <input type="checkbox"/> License Condition
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2. REGION I RESPONSE

<input type="checkbox"/> Immediate Site Inspection <input type="checkbox"/> Special Inspection <input checked="" type="checkbox"/> Telephone Inquiry <input type="checkbox"/> Preliminary Notification/Report <input type="checkbox"/> Information Entered in RI Log <input type="checkbox"/> Report Referred To:	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">Inspector/Date</td><td></td></tr> <tr><td>Inspector/Date</td><td></td></tr> <tr><td>Inspector/Date</td><td>Michael Reichard 3/28/19</td></tr> <tr><td></td><td>Daily Report</td></tr> <tr><td></td><td>Review at Next Inspection</td></tr> </table>	Inspector/Date		Inspector/Date		Inspector/Date	Michael Reichard 3/28/19		Daily Report		Review at Next Inspection
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	Daily Report										
	Review at Next Inspection										

3. REPORT EVALUATION

<input checked="" type="checkbox"/> Description of Event <input checked="" type="checkbox"/> Levels of RAM Involved <input checked="" type="checkbox"/> Cause of Event	<input checked="" type="checkbox"/> Corrective Actions <input checked="" type="checkbox"/> Calculations Adequate <input checked="" type="checkbox"/> Additional Information Requested from Licensee
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4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

<input type="checkbox"/> Release w/Exposure > Limits <input type="checkbox"/> Repeated Inadequate Control <input type="checkbox"/> Exposure 5x Limits <input type="checkbox"/> Potential Fatality <input type="checkbox"/> If any of the above are involved: <input type="checkbox"/> Considered Need for IIT Decision/Made By/Date:	<input type="checkbox"/> Deliberate Misuse w/Exposure > Limits <input type="checkbox"/> Pkging Failure > 10 rads/hr or Contamination > 1000x Limits <input type="checkbox"/> Large# Indivs w/Exp > Limits or Medical Deterministic Effects <input type="checkbox"/> Unique Circumstances or Safeguards Concerns <input type="checkbox"/> Considered Need for AIT
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5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

<input type="checkbox"/> Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose) <input type="checkbox"/> Medical Consultant Used-Name of Consultant/Date of Report: _____ <input type="checkbox"/> Medical Consultant Determined Event Directly Contributed to Fatality <input type="checkbox"/> Device Failure with Possible Adverse Generic Implications <input type="checkbox"/> HQ or Contractor Support Required to Evaluate Consequences
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6. SPECIAL INSTRUCTIONS OR COMMENTS

<input type="checkbox"/> Non-Public, MD 3.4 non-public _____	Inspector Signature: <u><i>Michael Reichard</i></u>	Date: <u>3/28/19</u>
<input checked="" type="checkbox"/> Public-SUNSI REVIEW COMPLETE	Branch Chief Initials: <u><i>AR</i></u>	Date: <u>4/9/19</u>

NMED 190040

Issue:

Conductivity was above the reporting limits of 10 CFR 36.83(a)(10), "pool water conductivity exceeding 100 microsiemens per centimeter."

A chiller failure resulted in oil in the pool. As a result, conductivity exceeded the reporting limit of 100 microsiemens/cm to a peak value of 180 microsiemens/cm.

Note: The 20 microsiemens/cm referenced by the licensee is the design parameter of the purification system required by 10 CFR 36.33(e). Not an operating regulatory limit.

Cause:

An independent evaluation was performed by a refrigeration consultant. The chiller failed due to a lack of water flow. Water flow was reduced due to saturated filters. The flow sensor had failed, which was not required to be checked under the licensee's procedures or NRC requirements. The flow sensor and the chiller have been replaced.

Corrective Action:

NRC notification was made within 24 hours. Oil was removed from the surface of the pool by suction. The saturated filters were replaced. The failed flow sensor was replaced. Conductivity was restored to acceptable levels, less than 20 microsiemens/cm. The chiller was replaced.

Preventative Actions:

Weekly verifications of the flow sensor was added to the routine maintenance procedure. The licensee is in the process of installing a digital communication system between the chiller and the online monitoring system to improve the timeliness of identifying these types of issues.

Extent of Condition:

N/A

Regulatory Disposition:

No violations were identified.

Additional Information Requested by NMED

February 21, 2019

U.S. NRC Region I
2100 Renaissance Blvd., Suite 100
King of Prussia PA 19406-2713

License No. 52-21175-01
Docket No. 030-19882
Baxter Healthcare of Puerto Rico – Aibonito Plant

Subject: Pursuant to the requirements of 10 CFR 21 § 36.83. Written Report for Notification 53839, Irradiator Pool Water Conductivity Exceeds Limit

Background

Per Nordion requirements, an irradiator water pool must be maintained in a temperature range between of 60-85 °F. To maintain the required temperature, a water chiller is used. Baxter's current chiller is a 30 Ton unit manufactured by Carrier, model 30RAN030—611KA and serial 4109Q57952. The closed system includes the chiller, filtration/treatment system, pumps and the pool. This system is necessary to provide water circulation to ensure temperature and water purity are in compliance with Regulation 10 CFR 21 § 36.63 and Nordion requirements. Temperature and conductivity meters are utilized to provide inline monitoring and continuous readings of water conditions.

Description of the Event

On Monday 21-Jan-2019, irradiator operators performing weekly safety checks and maintenance activities, reported oil floating on top of the pool water and in the filtering cartridges. Upon further investigation, the source of the oil was from a failure in the cooling section of the chiller. The "from pool" conductivity meter was saturated and non-operational, while the "to pool" conductivity meter was functional and showed a value of 180 microsiemens per centimeter.

The water conductivity value exceeded the requirement of 20 microsiemens per centimeter. Recorded values reached 180 microsiemens per centimeter as noted above.

At no time during this event, was there an increased risk for radiation exposure to employees or the public. The integrity of the shielding provided by the pool water was not impacted.

As of February 4, 2019, the irradiator has been operating within the permit requirements.

Immediate Actions Taken

NRC was notified by phone within 24 hours of the incident and event number 53839 was generated.

The site implemented corrective actions including: (1) removing oil from water; (2) adding water to the pool; (3) continuously filter the pool water with a filtration treatment and (4) frequent cartridges changes (4-5 days of use). Over the week, as these steps were implemented and had time to take effect, these steps were effective in correcting the water quality. At present, the incident has been corrected and the site is operating pursuant to its permits.

As an immediate action, after discovering the incident, the section of piping that allows water to enter the chiller was closed. Water circulation was maintained between the pool, pumps and water filtering/treatment system only. Oil on top of the pool was removed by suction, while fresh water was added to maintain the required water level and shielding. A radiation meter was placed adjacent to the technician to measure background levels of radiation while this activity was being performed. The source was kept in the safe storage position and water levels maintained as required during the oil removal process. Saturated filter system cartridges were replaced with new units and the filtering process resumed the same day. On 22-Jan-2019 the system and water condition were re-evaluated. The "from pool" conductivity meter was still saturated and non-operational. The other conductivity meter used to measure the water returning to the pool was functional and showing values

of 160 microsiemens per centimeter. As of February 4, 2019, the pool measurements were once again operating within all parameters of the permit.

The following table summarizes the conductivity levels and water addition to the pool for the current year 2019. Since February 4, 2019, the water conductivity was below requirements.

Weekly Inspection	Conductivity to Pool (microsiemens/centimeter)	Conductivity from Pool (microsiemens/centimeter)	Water Addition (gallons)
Jan 7, 2019	1.8	3.4	0
Jan 14, 2019	2.2	2.1	2
Jan 21, 2019 (event was reported)	Not available (saturated with oil)	Not available (saturated with oil)	0
Jan 28, 2019	51.4	24.7	593
Feb 4, 2019	6.7	3.3	29
Feb 11, 2019	5.6	5.9	80
Feb 18, 2019	1.1	0.1	56

Corrective Actions Taken

An analysis was completed to identify the root cause of the event and determine both corrective and preventive actions.

The failed chiller was evaluated by a refrigeration contractor (Benitez Refrigeration). The report indicated that the cooler section of the chiller failed due to lack of water flow. The flow sensor (DP switch) that measures the water entering the chiller was defective and did not activate. An installation of a new chiller was recommended. An emergency order for a new chiller was placed. The chiller is currently in transit to the site. Estimated completion date: **March 22, 2019**.

The remaining oil in the water was removed with continuous filtration/treatment and frequent cartridges changes while additional water was added to the pool.

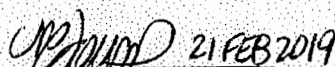
Preventive Action Plans

Preventive actions will be implemented in March 2019 along with the installation of the new chiller system. These actions include the following items:

- Addition of new chiller into the Plant Preventive Maintenance Program to minimize the risk of future chiller failures.
- A flow sensor (DP switch) will be added to our routine inspection program.
- To improve response time to changes in the water control system, the site will be installing an improved digital communication between the chiller and Metasys (the online monitoring system).
- Begin weekly tracking of pool water condition with control charts, in addition to the current NRC requirements for tracking.

If you have any questions, or require additional information, please do not hesitate to contact the undersigning at 787-735-8021, extension 2455.

Sincerely,


Marco Torres
Radiation Safety Officer

Baxter Healthcare of Puerto Rico
Medical Products
PO Box 1389
Aibonito, P.R. 00705