PDR

I.V. Systems Division

Baxter Healthcare Corporation
of Puerto Rico
P.O. Box 1389
Aibonito, Puerto Rico 00705

809.735.8021

Baxter

BAXTER QUALITY AWARD
1995 RECIPIENT

November 19, 1996

United States
Nuclear Regulatory Commission
Region II
Bruce S. Mallett, Director
101 Marietta Street, N.W. Suite 2900
Atlanta Georgia 30323-0199

Subject: Reply to Confirmatory Action Letter Issued on October 31, 1996

Gentlemen:

This is in reference of the inspection conducted by Jay Hansen and José Díaz of the NRC office on October 29, 1996.

Below is the reply to the items as listed on the Confirmatory Action Letter dated October 31, 1996.

ITEM 1
Performance check on each safety system was conducted on October 30, 1996 in order to verify all safety devices of our irradiator with satisfactory results. (See annex I).

ITEM 2
On November 1st, 1996 Mr. Vattan Eskibashian from Nordion reviewed the actual on-built configuration of our irradiator safety systems and found that meet the Nordion design requirements. Functional inspection of all safety systems was done to check for proper response and these were found to be satisfactory. (See annex II)

ITEM 3
All irradiator operators and support personnel were re-trained in a classroom environment on radiation safety at irradiation facilities, such as limitation on repairs and/or alterations to safety system as specyfied in license condition 14. In addition the personnel were re-trained on other safety topics. (See annex III).

ITEM 4
Part of the carrier safety interlock switch is preserved at Aibonito facility for further analysis if required by USNRC.

Baxter

We are submitting the above response to the items as listed on the Confirmatory Action Letter for your review and advise.

Should you have any questions, please contact us at your earliest convenience.

Sincerely,

Edwin A. Betancourt
General Manager

Luis A. Alvarado
Operations Manager

jc

BAXTER HEALTHCARE, CORP.
AIBONITO, P.R.

REF. SOP: 07-07-009

ISSUE DATE: 8/18/94

ITEM	SAFETY CHECKS FOR RADIATION STERILIZERS DESCRIPTION OF ITEMS TO BE CHECKED	OK	OTHER
	CHECKS FOR THE MAZE DOOR		
1	Attempt to open the maze door with the source in the "UP" position. The door should not open.	ok	
2	Attempt to open the maze door with the source in the "DOWN" position. The door should not open.	ok	
3	Attempt to open the maze door using the "MACHINE" key with the source in the "DOWN" position. The door should not unlock.	ok	
4	Attempt to open the maze door using the "MACHINE" key while pressing the radiation monitor test button with the source in the "DOWN" position. The door should not unlock.	ok	
5	Attempt to open the maze door using the "MACHINE" key after checking the radiation monitor with the source in the "DOWN" position. The door should now unlock and open.	ok	
6	With the source in the "DOWN" position, using a spare meter place the test source from the maze door lock box on the probe of the irradiation room monitor. The "IRRADIATION ROOM ALARM" should sound. Using the "MACHINE" key, a second operator, RSO, or designated person, should attempt to open the maze door according to the "Cell Entry Procedures". The door should not unlock. The first operator should then attempt to open the door from the inside. The door should open.	ok	
7	Attempt to start the irradiator with the maze door "OPEN". The irradiator should not start up.	ok	
	CHECKS FOR RADIATION MONITORS		
8	Irradiation Room Monitor. Described under "Checks for the Maze Door".	ok	
9	Exit Maze Monitors. Place the test source from the maze door lock box on the cover of the first "Exit Maze Monitor". The "EXIT MAZE ALARM" should sound, the fault indicator should illuminate, and the system should shut down. Repeat the procedure for the second monitor. NOTE: The source should be in the "UP" position in order to perform the check.	ok	
10	Deionizer Bed Monitors. Place the test source from the maze door lock box on the cover of the first "Deionizer Bed Monitor". The "DEIONIZER BED ALARM" should sound, the fault indicator should illuminate, and the system should shut down. Repeat the procedure for the other monitors. NOTE: The source should be in the "UP" position in order to perform the check.	ok	
11	Control Room Monitor. Place the test source from the maze door lock box on the cover of the "Control Room Monitor". The "CONTROL ROOM ALARM" should sound, the fault indicator should illuminate, and the system should shut down. Repeat the procedure for the other monitors. NOTE: The source should be in the "UP" position in order to perform the check.	ok	
12	Irradiation Room Probe. Initiate irradiator start-up. As the source begins to rise, depress the "Monitor test" button on the console and observe the ratemeter on the irradiation room monitor. The needle should move to full scale and remain there as long as the button is depressed. If the needle fails to reach full scale or drops from full scale, the probe is defective and should be replaced. After five (5) seconds, the button should be released and the needle should return to the normal position.	ok	
	CHECKS FOR STORAGE POOL		
13	Radiation Level. With the source in the "DOWN" position, check the radiation level at the pool surface and record. If the radiation level is above .1 Millirem/hour contact the local RSO.	ok	
14	Low and High Water Level Alarms. Depress the pool water level alarm switches for low and high water. Audible and visual alarms should sound at the control panel.	ok	

ITEM	SAFETY CHECKS FOR RADIATION STERILIZERS REF. SOP AI-07-07-009 DESCRIPTION OF ITEMS TO BE CHECKED CHECKS FOR OTHER COMPONENTS	OK	OTHER
15	Emergency pull cable. With the source in the "DOWN" position, attach a pull wire to the emergency pull cable. Execute normal "Irradiator Start Up Procedures". When the source begins its travel to the "UP" position, pull the wire. The system should shut down, the source should return to the "DOWN" position, and the "STOP" fault indicator should illuminate. Repeat this check for each emergency pull cable.	OK	
16	Emergency Stop Button. With the source in the "UP" position, press the "Emergency Stop" in the control room. The system should shut down, the source should return to the "DOWN" position, and the "STOP" fault indicator should illuminate.	OK	
17	Conveyor Stop Buttons. With the source in the "UP" position, press one of the "Conveyor Stop" buttons. The conveyor should stop and the system should shut down due to lack of available carrier at the entry position and/or lack of empty position at the discharge position when the dwell timer expires. If the entry position already had an available carrier and the discharge was already clear, the system should not shut down until the second expiration of the dwell timer. For the other three "Conveyor Stop" buttons, verify that each button is effective in stopping carrier movement in the load/unload area.	OK	
18	Safety Timer. With the source in the "DOWN" position, attempt to start up the irradiator but let the 90 second safety timer expire before turning the "MACHINE" keyswitch to the "ON" position. The irradiator should not start up.	OK	
19	Source Hoist Air Interlock. Attempt to start-up the irradiator with the source hoist air interlock disconnected. The irradiator should not start up.	OK	
20	Source Leakage. Measure the radiation level at the deionizer bed filter with the Berthold Rato/F meter and record. If the radiation level above .2 Millirems/hour contact the local RSO.	OK	
21	Carrier Collision Device. With the source in the "DOWN" position, and using the hand control with the console maintenance switch in the "MANUAL" mode, press the "SVPI, A, B, C DISCH" rocker switch on the hand control. A second operator, RSO, or designated person should hit the carrier collision device mounted at the near end of the source rack. When activated, the cylinder(s) moving the carrier(s) must return to the receive position and the appropriate fault indicator will illuminate on the control console. Repeat this check for the carrier collision device mounted at the far end of the source rack.	OK	
22	Check for exit maze switching runner. With the source in the "UP" position, and using a long pole, press the switching runner located at the exit maze floor. The system should shutdown, the source should return to the "DOWN" position, and the "IN-OUT BARR DOOR" fault indicator should illuminate.	OK	
23	Back up access. With the source in the "UP" position, and using a long pole, interrupt the path of the electronic eyes of the back up access control system at the product exit door. The system should shutdown, the source should return to the "DOWN" position, and the "IN-OUT BARR DOOR" fault indicator should illuminate. Repeat procedure with the system located at the product entrance door.	OK	
24	Back up access personnel entry door. Interrupt the path of the electronic eyes at the personnel entry door. With the source in the "DOWN" position, attempt to raise the source. The irradiator should not start.	OK	

PERFORMED BY:	D. Chavez	DATE PERFORMED:	10/30/96.
REVIEWED BY:	J. Olivas	DATE OF REVIEW:	10-30-96

A Tradition of Excellence
1946-1996

NORDION INTERNATIONAL INC.

ANNEX 2-A

Baxter HealthCare . Inc.
Attn: Mr Luis Alvarado
Operations Manager
P . O. Box 1389
State Road 721 , Km 0.3
Aibonito , Puerto Rico 00705

November 6 , 1996

Dear Mr Alvarado ,

Mr Vahan Eskibashian from our insallation and service department performed a thorough inspection of your irradiator safety systems on November 1 , 1996 . He provided you with a copy of his inspection report for your records .
The as - built configuration of your safety system was reviewed on site and found to meet the Nordion design requirements . A functional inspection of all safety systems was done to check for proper responses and these were found to be satisfactory .

Two additional safety systems have been added to the machine and these were also checked for proper operation and found to be satisfactory . These systems were the following :

1. Photo sensors to stop the operation of the hydraulic load / unload elevator in the storage system if a person approaches it too closely . This system is wired to the outside storage conveyors and should not influence the irradiator safety control systems .

2. Warning light and horn in the storage area to provide an alarm if the product exit area monitor indicates higher than background radiation levels .

Nordion engineers will further review the wiring of these two systems as soon as we receive the drawings which you intend to fax to us by Friday November 8 , 1996 .

The operators that have received training at the Canadian Irradiation Center in the safe operation and maintenance of irradiators , should be able to perform routine maintenance tasks that include replacement of parts that are faulty , so long as the parts conform with Nordion specifications . They should not be authorized to use substitute parts or make changes to safety systems without authorization from Nordion .

Yours Sincerely ,
R G McKinnon
Chief Engineer
Quality Assurance Department

cc . D McKinney - Nordion
J Stirling - Nordion

447 March Road, Kanata, Ontario, Canada K2K 1X8 Tel.: (613) 592-2790 Fax: (613) 592-6937

NORDION INTERNATIONAL INC.

RECORD OF INSPECTION
(Production Irradiators - Ref: IN/IM 0166 IR000)

1 MONITORS

		See Note 1	
1-1	Hand survey meter (attached to power key)	✔	✓
1-2	Test Source installed in keyswitch	✔	✓
1-3	L118 Monitor		
1-3-1	L118 Monitor Alarm with Test Source	✔	✓
1-3-2	L118 Monitor Personnel Access Door Interlock	✔	✓
1-4	L118 Monitor Saturation Test	✔	✓
1-5	Personnel Access Door Opens from Inside	✔	✓

2 FAULT INDICATORS

2-1	Source Pass or Internal Conveyor Fault		✓
2-2	Overdose Timer		✓
2-3	Source Rack Faults		
2-3-1	Up		✓
2-3-2	Down		✓
2-4	Maze Area Monitors LUDLUM	✓	✓
2-4-1	Area Monitor #1 (See Note 2)	✔	✓
2-4-2	Area Monitor #2 (See Note 2)		✓
2-5	Low Air		✓
2-6	Load/Unload Fault		N/A
2-7	Stop Conditions		
2-7-1	Emergency Pull Cable (COS 1)	✔	✓
2-7-2	Emergency Pull Cable (COS 2) EMERGENCY (COS) 3	✔	✓
2-7-3	Roof Plug (inside)	✔	✓
2-7-4	Roof Plug (outside)	✔	✓
2-7-5	Stop Button on Console	✔	✓
2-7-6	Optional Stop Buttons	✔	N/A
2-7-7	Personnel Access Door Interlock	✔	✓
2-8	High Temperature Fault		
2-8-1	High Temp. Sensor #1		✓
2-8-2	High Temp. Sensor #2		✓
2-9	Exhaust Fan Fault		
2-9-1	Fan #1		✓
2-9-2	Fan #2		✓
2-10	Product Barrier Door Fault		
2-10-1	Inlet Door	✔	✓
2-10-2	Outlet Door	✔	✓
2-11	Deionizer Area Monitors		
2-11-1	Area Monitor #3 (See Note 2)	✔	✓
2-11-2	Area Monitor #4 (See Note 2)		N/A
2-12	Earthquake Detector		✓
2-13	Smoke Detector		✓
2-14	Research Loop Door Interlock	✔	N/A
2-15	Carrier Collision Device (Source Pass)	✔	✓
2-16	Product Movement Timer (PMT) (Overdose)		✓
2-17	Source Valve Sequence Fault		N/A
2-18	Source Valve Sequence Check		N/A
	DL2 MAZEDOOR AREA		✓

Note 1: All items checked off in this column (shown with a ✔) are mandatory for personnel safety. Any deficiencies require immediate notification by fax or telex to Nordion Kanata, attention Radiation Safety Officer.

Note 2: If multiple area monitors are used, at least one area monitor must be operational. If not, immediate notification is required (See Note 1).

NORDION INTERNATIONAL INC.

3 ALARMS AND LIGHTS

	See Note 1	
3-1 Monitor Alarm (L118)		
3-1-1 L118 Monitor Buzzer	✔	✓
3-1-2 L118 Monitor Lights		✓
3-2 Source Moving Bell, Flashing Beacon Light, and Buzzer	✔	✓
3-3 Radiation Warning Light(s)	✔	✓
3-4 Safety Start-up Flashing Beacon Light and Buzzer	✔	✓
3-5 Control Console		
3-5-1 Operating Lights		✓
3-5-2 Source Position Lights	✔	✓
3-6 Low Water Alarm	✔	✓
3-7 Interim Area Not Clear		N/A

4 MISCELLANEOUS

		See Note 1
4-1 Product ~~Tensioner~~ Carriers	✔	✓
4-2 Water Deionizer From Pool Reading	60000 Ω 16.6 µMho	✓
4-3 Guide Cable Condition and Tension	✔	✓
4-4 Source Hoist Cable Condition	✔	✓
4-5 Power Failure		✓
4-6 Source Hoise Switch Actuations		✓
4-7 Safety Start-up Time Delay (max. 90 sec.)	✔	✓
4-8 Pneumatic Source Hoist Interlock Chain	✔	✓
4-9 Source Rack Up and Down Counter Reading		67/89
4-10 Check Customer Log Book		✓
4-11 Backup Access Control		
4-11-1 Door Entry Access		✓
4-11-2 Inlet Entry Access		✓
4-12 Personnel Training Records (Check Customer Record of Trained Personnel)		
(a) Is list current? Y or N		Y
(b) Any new staff? Y or N /		Y
(c) If new staff, have they received training? Comments: MARCH 96 IN HOUSE TRAINING		Y
4-13 Source Hoist Valve Exhausts		✓
4-14 Filter Bank(s)		✓
4-15 Design Changes		
Design Changes Made? Y or N		Y
Description Obtained? Y or N		Y

BAXTER
Customer Name

130
IR. NO.

PUERTO RICO
Customer Address

Signed (Nordion)
V. ESKIBASHIAN

1-11-96
Date

Oscar Camacho
Signed Customer OSCAR CAMACHO-RSO

Deficiencies marked with an asterisk * must be corrected by: _____

A signed copy of Record of Inspection is to be returned to Nordion upon completion of all corrective action on or before this date. Failure to comply will result in the notification of Local Competent Authority.

Signed Customer _____ Title _____ Date _____

Customer Note: Items marked "SI" are safety improvements incorporated in the design or are regulatory requirements since your machine was installed. We strongly urge you to have them installed on your facility.

Baxter

Irradiation Facilities Safety Training (Topics Discussed)

Aibonito

- Materials License
- Irradiation Emergency & Abnormal Event Procedures
- Irradiation Operating Procedures
- Personnel Monitoring for Radiation Exposure (14-07-08-001)
- Equipment Maintenance Procedures for Radiation Sterilizers (16-07-09-002)
- Radiation Equipment Calibration Procedures (20-04-02-237)
- Irradiation Operations Log (20-08-02-258)
- Irradiation Maintenance Log (20-08-02-259)
- Cell Entry Procedure
- Gamma Irradiation Systems & Security Codes (AI-07-07-009)

Baxter Quality Award

1995 RECIPIENT

ANNEX 3B

BAXTER HEALTHCARE CORPORATION
AIBONITO, P.R.

Hoja de Asistencia de Adiestramiento

REF. SOP: AI-01-02-009 ISSUE DATE: 6-7-96 REF. SPEC. 50-19-06-001

TITULO DE ADIESTRAMIENTO	CODIGO	FECHA DE COMIENZO
Irradiation facilities Safety training		11/6/96
	TIEMPO EN DURACION (HORAS) 2.0	FECHA DE TERMINACION 11/6/96
SUMINISTRADO POR: Juan Rivera		NUM. ASOCIADO: 13487

CLASIFICACION / SEXO

NUM. ASOCIADO	NOMBRE (LETRA DE MOLDE)	FIRMA	REG.	TEMP.	H R	B I	ADM	M	F	NUMERO SEGURO SOCIAL	DEPT.
713826	Efraín Santiago	E. Santiago				✓		✓		584-14-0181	Gamma
714222	JESUS SUAREZ	J. Suarez				✓		✓		581-13-7010	GAMMA
713993	Miguel Abraham	M. Abraham			✓			✓		583-80-1609	Gamma
713873	David Maldonado	D. Maldonado				✓		✓		583-86-1536	"
13820	RAUL CARDIN	Raul Cardin					✓	✓		582-66-4992	Gamma
13575	Myriam Ramirez	M. Ramirez					✓		✓	583-28-8759	Quality
713576	Oscar Camacho	O. Camacho					✓	✓		584-10-2803	Gamma
99061	ANGEL ALICEA	A. Alicea					✓			583-06-7235	GAMMA
77317	Lourdes Rivera	L. Rivera				✓			✓	584-48-9078	Q
713785	Ramón L. Rivera	R. L. Rivera			✓			✓	✓	584-68-6645	MANT.
714255	Cesar de Torres	C. de Torres	✓		✓			-	-	584-80-0997	fac.
713911	Antonio Fernández	A. Fernández	-		-			✓		583-07-4781	FAC.
713874	Guillermo Muñiz	G. Muñiz	✓		✓			✓		583-72-9393	FAC.
	Firma Asociado:										
	Firma Autorizada:	Marta Rosario 11-8-96									

FIRMA DEL INSTRUCTOR I Juan Rivera

FIRMA DEL INSTRUCTOR II

DEPARTAMENTO DE ADIESTRAMIENTO

ENTRADO POR FECHA

FORM AI-PD-001-219 10/95