

I.V. Systems Division

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

809.735.8021

PDR 3019882  
-21175-01  
(2-96-016)  
CC: EICS

**Baxter**

February 13, 1997



BAXTER  
QUALITY  
AWARD

1995 RECIPIENT

Bruce S. Mallet  
United States Nuclear Regulatory Commission  
Region II  
101 Marietta Street  
N. W. suite 290C  
Atlanta, Georgia 30323-0199

Subject: Reply to Your Letter dated December 4 1996

Gentlemen:

This is in reference to the two issues that you requested clarification in your letter dated December 4 1996.

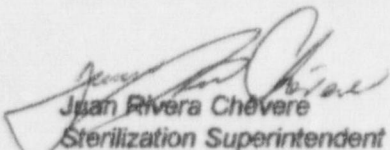
ITEM NO. I

- According to Nordion Techniciens, the testing of the inner roof plug switch should be checked every three months. We, at Baxter, agree with them and we are going to include this check on the quarterly checks as per Baxter Specification '16-7-9-2" Equipment Maintenance Procedure for Radiation Sterilizers.

ITEM NO. II

- Regarding the photo sensor stop circuit of the outside load/unload conveyor elevator; this stopped the operation of the hydraulic load/unload elevator in the storage area if a person approached it too closely. This system is not wired to the outside storage conveyors and should not influence the irradiation safety control system.
- The product exit area radiation monitor warning light is correctly integrated into the existing circuit.

See memo and drawings attached.

  
Juan Rivera Chavere  
Sterilization Superintendent

/cic

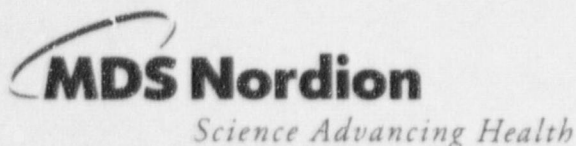
attach.ments

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PDR ADOCK 03019882  
C PDR



ML20

March Road  
Kanata, Ontario  
Canada K2K 1X8  
Tel: 613 592-2790



Baxter HealthCare Inc  
P.O. Box 1389  
State Road 721, Km 0.3  
Aibonito, Puerto Rico  
00705

Attention : Mr. Juan Rivera Chivere

This is to confirm our discussion regarding the routine testing of the inner roof plug switch . I agree that testing this switch on a monthly basis may be too frequent because it is situated over the pool and can be very awkward to get at and could create a hazard to the inspector . I do believe it should be checked periodically in between source reloads which happen annually at your facility . every three months would probably be an acceptable time frame .

Yours Sincerely ,  
R.G.McKinnon ,  
Chief Engineer ,  
Quality Assurance Department .

A handwritten signature in dark ink, appearing to read 'R.G. McKinnon', is written over the typed name.

MDS Nordion  
447 March Road  
Kanata, Ontario,  
K2K 1X8

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

Mr. Alvarado

I have reviewed the drawings which were sent to us. These drawings describe changes that have been incorporated into your irradiator control systems. The changes are described as follows:

1. Photo sensors to stop operation of hydraulic load and unload elevators in the storage area.
2. Warning light and horn in the storage area to provide alarm if product exit monitors alarm.

The first change, photo switch on the elevators, is unclear in what part of the circuit this applies. I have revised a copy of the section of the schematic that it appears to apply to, please see first attachment. If this is the case, and I have interpreted your sketch correctly, then it would appear that the solenoids for the elevators would rely on having a light bulb in place to operate. While this is not a safety concern it would be a reliability problem, for example the elevator would not work when the light bulb burnt out. You may choose to use a different set of contacts of relay R to illuminate the light, see second attachment.

The second change, the DL2 warning light, is correctly integrated into the existing circuit. I do not see any problems with this circuit.

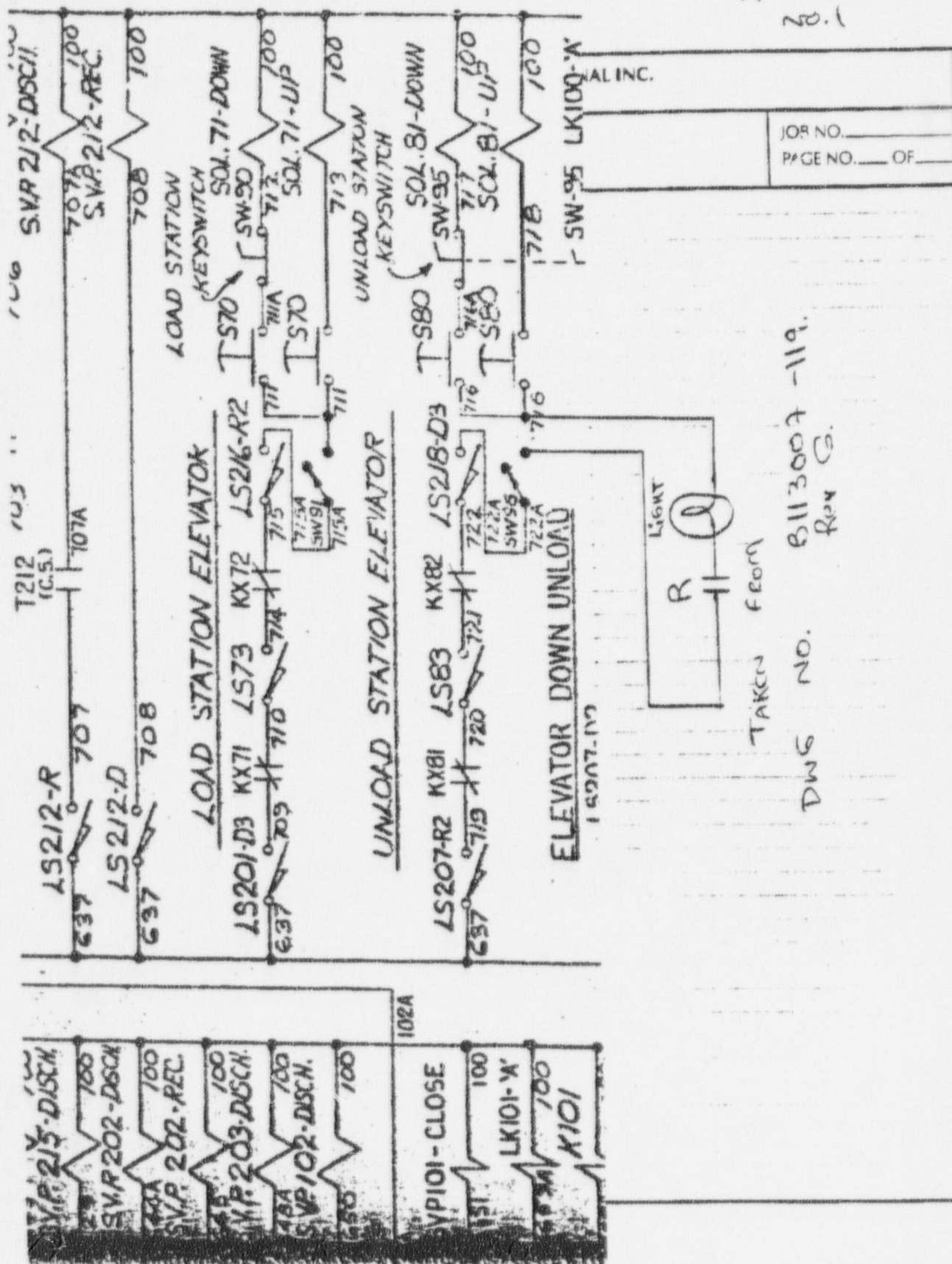
I would appreciate a reply on how you intend to deal with the photo sensor circuits.

Sincerely,

Nino Bascelli  
Development Officer



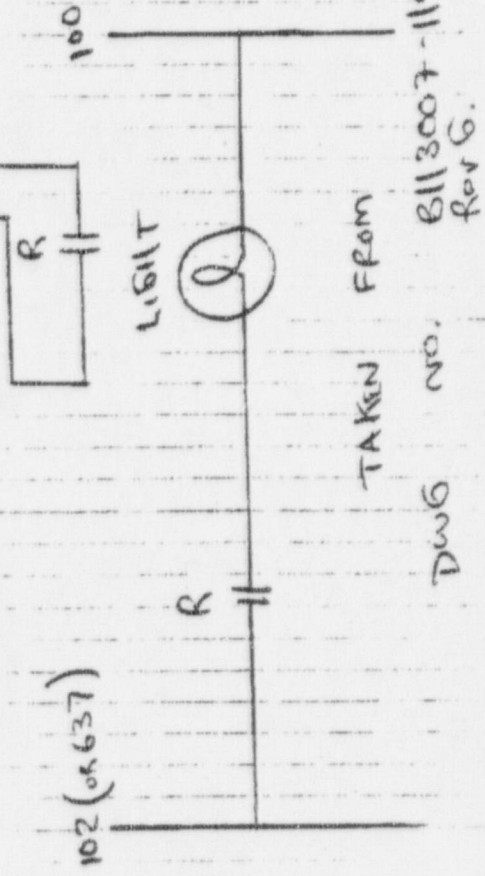
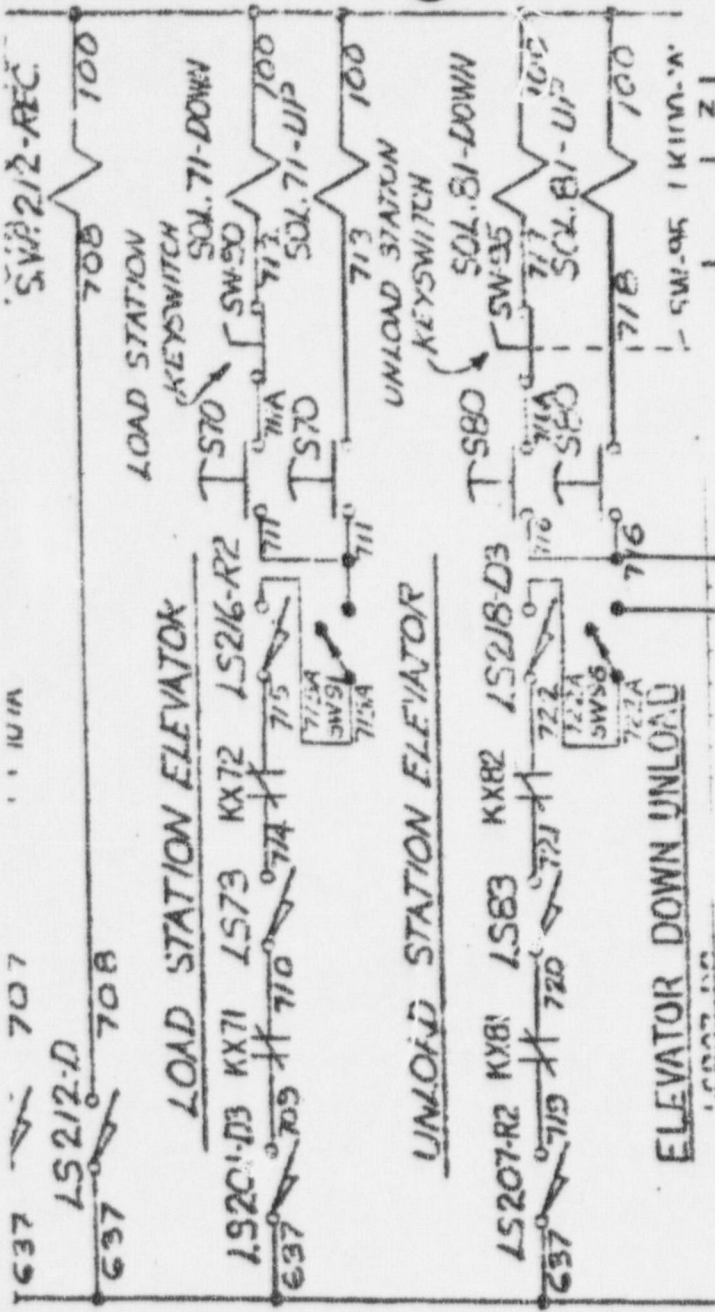
ATTACHMENT  
NO.1



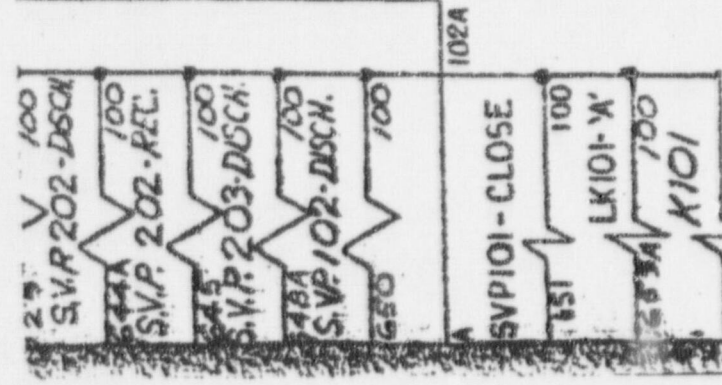
ATTACHMENT  
NO. 2

NATIONAL INC.

JOB NO. \_\_\_\_\_  
PAGE NO. \_\_\_\_\_ OF \_\_\_\_\_



TAKEN FROM  
DWG NO. B113007-119  
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1946-1996



**NORDION**  
INTERNATIONAL INC.

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 installation 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