



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555

12-15-92

MEMORANDUM FOR: Richard E. Cunningham, Director  
Division of Industrial & Medical  
Nuclear Safety  
Office of Nuclear Material Safety  
and Safeguards

FROM: Carl J. Paperiello, Leader  
Incident Investigation Team

SUBJECT: LICENSING AND INSPECTION GUIDANCE PROVIDED BY  
NMSS TO THE REGIONS

As you are aware, the Incident Investigation Team I am leading is investigating the failure of a High Dose Rate Remote Afterloader which led to a misadministration and the loss of the source. As part of our investigation we must review NRC effectiveness in regulating this activity. I am requesting that you provide us with the applicable licensing and inspection guidance provided to the Regions by NMSS as of November 30, 1992. I would appreciate this as soon as possible.

A handwritten signature in cursive script that reads "Carl J. Paperiello".

Carl J. Paperiello, Leader  
Incident Investigation Team

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

December 7, 1992

CAL No. 1-92-018

Omnitron International, Inc.  
ATTN: Richard V. Calfee, Ph.D.  
President and Director  
8990 Kirby Drive, Suite 200  
Houston, Texas 77054

Dear Dr. Calfee:

This refers to the conversation between you and Drs. Carl J. Paperiello and Mohamed Shanbaky of the U.S. Nuclear Regulatory Commission (NRC) on December 4, 1992, at the Indiana Regional Cancer Center. This conversation concerned the diagnosis by Omnitron International, Inc., of the apparent failure of an Omnitron Model 2000, Serial Number 0100, High Dose Rate (HDR) Afterloader at the Indiana Regional Cancer Center. This device is marketed, distributed and used in locations subject to the NRC's jurisdiction. We also discussed your obligations under 10 CFR Part 21.

Based on the above discussion, it is our understanding that you have taken or will take the following actions, which will be completed by the dates specified:

1. The HDR's active wire will be tested to determine the probable cause(s) of the wire failure. Tests are anticipated to be completed by December 23, 1992.
2. Prior to performance of the tests, Omnitron will provide detailed written testing procedures including methods and equipment used for each test that will be performed. This will be submitted by overnight mail or delivery service to:

U.S. Nuclear Regulatory Commission  
ATTN: Dr. Carl J. Paperiello, NRC-IIT Team Leader  
7735 Old Georgetown Road  
Bethesda, Maryland 20814  
(301) 492-4848

Dr. Paperiello may be reached through the NRC Operations Center at (301) 951-0550.

3. The NRC Staff or any NRC representative will be permitted to observe all tests performed. You will notify the NRC-IIT Team Leader of all intended tests a minimum of three days prior to the performance of these tests. All test data, interpretation, and reports will be submitted immediately upon completion to the NRC-IIT Team Leader.

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4. No tests, maintenance, operations, or any modifications will be performed on the HDR unit without prior authorization from the NRC-IIT Team Leader.
5. Omnitron will issue a written notification/bulletin to all of their clients that own or use an Omnitron 2000 HDR unit describing the incident and providing any additional safety precautions including radiation monitoring of all patients after HDR treatment and prior to their release from the treatment area. This will also be submitted to the NRC-IIT Team Leader at the same time such notification/bulletin is issued to the users.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, and 10 CFR 2.204, you are required to:

1. Notify the NRC immediately if your understanding differs from that set forth above;
2. Notify the NRC if for any reason you cannot complete your investigation within the schedule specified in this Confirmatory Action Letter, dated December 7, 1992, and advise me in writing of your modified schedule in advance of the change; and
3. Notify the NRC in writing when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude the issuance of an Order formalizing the above commitments or requiring other actions on the part of Omnitron International, Inc., nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter.

The responses directed by this letter are not subject to the clearance procedures of the Office of Management and Budget, as required in the Paperwork Reduction Act of 1980, Pub. L. 96-511. In accordance with 10 CFR 2.790(a), a copy of this letter will be placed in the NRC Public Document Room.

Your cooperation with us is appreciated.

Sincerely,



Thomas T. Martin  
Regional Administrator

cc:

C.J. Paperiello, IIT Leader  
State of Louisiana  
State of Texas  
State of Ohio  
Commonwealth of Pennsylvania  
U.S. Food and Drug Administration  
Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)

bcc:

RI Docket Room (w/concurrences)  
IIT r/f  
J. Taylor, EDO  
H. Thompson, DEDS  
R. Bernero, NMSS  
D. Ross, AEOD  
M. Taylor, OEDO  
E. Jordan, AEOD  
J. Lieberman, OE  
J. Goldberg, OGC  
R. Cunningham NMSS  
A. Davis, RIII  
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R. Bellamy, RI  
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L. Callan, RIV  
D. Holody, RI  
M. Shanbaky, RI