

MARYLAND DEPARTMENT OF THE ENVIRONMENT
AIR AND RADIATION MANAGEMENT ADMINISTRATION
RADIOLOGICAL HEALTH PROGRAM

FACSIMILE TRANSMITTAL SHEET

TO:

Fred C. Combs
Deputy Director

FROM:

Ray Mankin

MDE - ARMA - Radiological Health Program
2500 Broening Highway - Baltimore MD 21224
(Phone) 410- 631-3300 410-631-3198 (fax)
or 1-800 633-6101 (in Maryland only)

Date:

4 126 12000

of pages (including this sheet):

16 18 pages

COMMENTS:

Additional NPI information

License Approval**MARYLAND DEPARTMENT OF THE ENVIRONMENT**

2500 Broening Highway • Baltimore Maryland 21224

(410) 631-3000 • 1-800-633-6101 • <http://www.mde.state.md.us>Parris N. Glendening
Governor
FYIJane T. Nishida
Secretary

RAY, ALAN, AND CARL RECEIVED A COPY OF THE
ATTACHED. AFTER YOUR REVIEW PLEASE RETURN TO
JANET TO FILE.

THANKS

MDE**MARYLAND DEPARTMENT OF THE ENVIRONMENT**

2500 Broening Highway • Baltimore Maryland 21224

(410) 631-3000 • 1-800-633-6101 • <http://www.mde.state.md.us>Parris N. Glendening
Governor**SEP 30 1999**Jane T. Nishida
Secretary**CERTIFIED MAIL**

Return Receipt Requested

License No: MD-31-025-03RHP Case No. 99-6Jackson A. Ransohoff, President
Neutron Products, Inc.
Mt. Ephraim Road, P.O. Box 68
Dickerson, Maryland 20842

Dear Mr. Ransohoff:

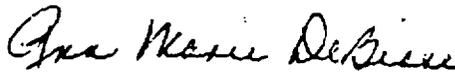
Enclosed you will find a Complaint and an Administrative Penalty against Neutron Products, Inc. resulting from violations of Maryland's law and regulations governing use of radioactive materials. The Air and Radiation Management Administration is assessing a penalty of \$35,000 in this case.

Please read the following paragraphs carefully, paying close attention to the time period for appeal. Additional information on requesting a hearing on the Complaint and Administrative Penalty can be found at the end of the enclosed document. If you elect to request a hearing on this matter, you must request such a hearing within thirty (30) calendar days following receipt of this document.

The assessment and amount of the penalty may increase or decrease as a result of the hearing. If payment of the penalty is elected, you should contact Ms. Deborah I. Kemp at (410) 631-4117 to arrange for an invoice to be sent to you for the above amount.

If you have any questions concerning this matter, please contact Mr. Carl E. Trump, Radioactive Materials Division, Air and Radiation Management Administration, at (410) 631-3300. However, if you have an attorney, please have your attorney contact the Assistant Attorney General whose signature appears on the enclosed document at (410) 631-3053.

Sincerely,



for Merrylin Zaw-Mon, Director
Air and Radiation Management Administration

Enclosure

cc: Office of the Attorney General
Deborah I. Kemp (w/o encl)
Ian J. Forrest
Licensee File

- (3) WHEREAS, Section 8-301(a) of the Environment Article and Maryland Regulations for the Control of Ionizing Radiation, incorporated at Code of Maryland Regulations ("COMAR") 26.12.01.01.C.1(a), requires that NPI shall obtain a license from the Administration in order to work with or use radioactive material; and
- (4) WHEREAS, COMAR 26.12.01.01 Section C.30 provides that the Administration may incorporate in the license terms and conditions regarding the receipt, use and transfer of radioactive materials, and COMAR 26.12.01.01C.31(c) provides that the licensee shall confine its use and possession of radioactive materials "to the locations and purposes authorized in the license;" and
- (5) WHEREAS, in accordance with NPI's application dated March 29, 1990, subject to Department revisions, and as supplemented from time to time through November 24, 1997, the Administration issued Licenses MD-31-025-03, which included certain terms and conditions; and
- (6) WHEREAS, under Sections 8-503 and 8-510 of the Environment Article, the Administration may impose a corrective order and/or a civil, administrative penalty for a violation of any radioactive material regulation or license; and
- (7) WHEREAS, in August and September of 1998, an inspector employed by the Administration, Mr. Raymond E. Manley and other Administration technical staff performed an investigation of the circumstances surrounding an over-exposure of an NPI field service engineer operating under the allowed uses of NPI License No. MD-31-025-03. During that investigation, the inspectors found the following violations:
- (a) On June 25-26, 1998 NPI failed to control the occupational doses to a team of teletherapy field service engineers while they were exchanging a radiation source and servicing a cancer therapy machine at Mount Sinai Medical Center of Greater Miami in Miami Beach,

Florida. During this exchange and servicing activity, the engineers conducted an unusual licensed activity involving multiple mirror adjustments of the teletherapy unit they were working on. One service engineer received a whole body total effective dose equivalent (TEDE) of 7.078 Rem, in violation of COMAR 26.12.01.01D.201(a) titled, "Occupational Dose Limits for Adults" which requires that NPI control the occupational dose to individual adults to an annual limit of 5 Rem or less.

(b) The NPI service engineer who received the overexposure on June 25-26, 1998 while conducting multiple mirror adjustments of a teletherapy unit was engaged in moving the radioactive material source to various distances away from its shielded position. This created substantial and significantly increased dose rates beyond what would normally have been expected in a cancer therapy source exchange. Even after a conference with the NPI Radiation Safety Officer and other experienced NPI service personnel, the on-site engineers failed to conduct adequate surveys, in violation of COMAR 26.12.01.01D.501, titled, "Surveys and Monitoring-General." This provision requires, in part, that each licensee make or cause to be made such surveys as may be necessary for him to evaluate the extent of radiation hazards that may be present.

(c) On June 25-26, 1998 NPI lost control of the source of radiation while exchanging the radiation source and servicing the cancer therapy machine at Sinai hospital in Miami Beach Florida. This caused an NPI service engineer to exceed 0.05 Sv. (5 Rem), the annual limit for occupational exposure. NPI's personnel dosimetry service company telephoned NPI's facility on August 7, 1998 and informed that the employee's whole body limit had been exceeded. NPI failed to report this overexposure to RHP until August 17, 1998, a period of 10 days after NPI became aware, in violation of COMAR 26.12.01.01D.1202(b) titled, "Notification of Incidents-Twenty-Four Hour Notification." This provision requires licensees to notify RHP in writing by

telegram, mailgram or facsimile, within 24 hours of discovery of the event, each event involving the loss of control of a source of radiation that may have caused, or threatens to cause, an individual to receive in a period of 24 hours, a total effective dose equivalent (TEDE) exceeding 0.05 Sv (5 Rem).

(d) NPI failed to conduct adequate radiation surveys during the mirror adjustments on June 25-26, 1998 resulting in the beam pattern from the radiation source not being properly defined. As a result, two of the participating engineers' whole body dosimeters were worn at belt level instead of mid chest level and therefore were not worn in the region of highest exposure. The lack of a proper survey was in violation of COMAR 26.12.01.01D.502 titled, "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose" which requires that a licensee monitor exposures sufficient to demonstrate compliance with the occupational dose limits of Part D.

(e) COMAR 26.12.01.01C.31(c) titled, "Specific Terms and Conditions of License" requires each person licensed by the Agency to confine use of the licensed material to purposes authorized in the license. NPI's License No. MD 31-025-03, Condition #14 requires NPI to follow their Specification P-9 titled, "Procedures for Source Transfer, Maintenance, and Service Associated with Teletherapy Devices" as revised March 29, 1990. NPI's specific license condition #17 incorporates NPI Specification P-9 revision 2 with Table I and Appendices I through IX. The following provisions of Specification P-9 were violated:

(1) NPI's Specification P-9, Page 4 No. 7 specifies the minimum radiation dose recording devices (dosimetry) to be worn by each member of a field service team at a site. That dosimetry is:

- (a) A self-reading integrating dosimeter (an SRD) capable of measuring at least 200 millirems in at least 5 millirem increments, as a low-range whole body dosimeter;
- (b) An SRD capable of indicating at least 1,000 millirems, as a high-range whole body dosimeter;
- (c) Two remote reading dosimeters (also known as a TLD), one read at the end of the month and the other, at the end of the quarter, measuring whole body doses;
- (d) A TLD for at least one wrist;
- (e) An SRD on each wrist, capable of measuring at least 10,000 millirems; and
- f) An audible personnel monitoring device.

Contrary to the above, on June 25, 1998, during the source exchange at Sinai, NPI personnel violated Specification P-9 in the following manners:

- (a) Two of the NPI service engineers wore only one SRD to measure whole body doses. This is contrary to the licensee's procedures that require the wearing of two whole body dosimeters (low range and high range).
 - b) One engineer stated that when he wore wrist SRDs, he wore a 1,000 millirem SRD on his left wrist and a 500 millirem SRD on his right wrist instead of the required 2 SRDs, each capable of measuring 10,000 millirem.
- (2) Also, Specification P-9, "Installation Operation," No. 14 and 15 on Page 7 require that the SRDs of team members are to be read and recorded after the service engineers replace the cover plates, collimators, retainer, and perform such maintenance as appropriate. The activity involving the adjustment of the mirror clearly falls into the category of "maintenance as appropriate." Contrary to this requirement, however:

(a) The senior engineer on site stated that whole body SRDs were last read and recorded following the source exchange and prior to the mirror adjustments thereby failing to record the highest portion of personnel exposures at the Sinai site;

(b) Following the source transfer and prior to the mirror adjustment, one of the engineers removed his whole body SRD. This action failed to allow for final reading of his SRD following the mirror adjustments; and

(c) Following the source transfer and prior to the mirror adjustment all three engineers removed their wrist SRDs. This action failed to allow for recording those dosimeters which would have recorded the highest portion of exposure at the Sinai site.

(3) Also, Specification P-9, "Installation Operation," No. 15 on Page 7 requires that the SRDs of team members are to be read and recorded on NPI's "Teletherapy Installation Notice Form". On that form, whole body SRD readings are taken from specific SRDs noted by SRD serial number, then assigned to the identification number of the individual being monitored. Unfortunately, the form specific to the June 25-26, 1998 Sinai cancer therapy source replacement, shows two users wearing an SRD with the same serial number and with the identical dose reading entered in the record. Of particular concern is that the whole body dosimeter record in question involves an individual who by interview participated in the mirror adjustment for a period of time almost two times greater than the overexposed individual. Also that individual's whole body TLD was located at the waist and out of the major collimated beam.

(f) COMAR 26.12.01.01J.12(a)(3) titled, "Instruction to Workers" requires all individuals working in or frequenting any portion of a restricted area to be instructed in , and

ADMINISTRATIVE PENALTY

The Air and Radiation Management Administration is assessing an administrative penalty in this case of \$35,000, based on the factors set forth in Section 8-510(b) of the Environment Article. These factors include the willfulness of the violations, the cost of control of the source of radiation, the economic reasonableness of correcting the violations, the extent to which the violations are part of a recurrent pattern of the same or similar type of violation, the extent to which the violations create the potential for harm to health, and the degree of hazard posed by the emission of radiation.

9/28/99
Date

Merrilyn Zaw-Mon
for Merrilyn Zaw-Mon, Director
Air & Radiation Management Administration

Approved as to form and
legal sufficiency this

3th day of

September, 1999.

Deborah Smith

Assistant Attorney General

From: Debra Smith
To: Ray Manley
Date: Wed, Nov 3, 1999 3:36 PM
Subject: Neutron

Ray I just wanted to follow-up on the Neutron hearing request.

Please send the OAH hearing request, but add one sentence to cover letter stating that we are not in agreement, at this time with consolidating the case with any pending cases. Neutron will probably file a motion for consolidation, which we can address at a later date. According to our statute we have a 50,000 cap per action. We would need an agreement that Neutron will waive 50,000 limit for any future appeals. I am not sure that Neutron would agree. Thanks for your help.

Debra A. Smith (x3039)
Assistant Attorney General
State of Maryland

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ATTORNEY GENERAL

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DEPUTY ATTORNEY GENERAL

CARMEN M. SHEPARD
DEPUTY ATTORNEY GENERAL

DENISE FERGUSON-SOUTHARD
PRINCIPAL COUNSEL

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WRITER'S DIRECT DIAL NO.
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STEPHANIE COBB WILLIAMS
JENNIFER L. WURZBACHER
NANCY W. YOUNG
ASSISTANT ATTORNEYS GENERAL

August 23, 1999

Molly Q. Ruhl
Clerk of the Circuit Court
Montgomery County Judicial Center
50 Courthouse Square
Rockville, Maryland 20850

Re: State of Maryland, Department of the Environment v. Neutron Products, Inc.,
Case No. 199036, Honorable Nelson W. Rupp, Jr.

Dear Ms. Ruhl:

Enclosed for filing in the above referenced case is the Plaintiff's Motion for Partial Summary Judgment and Scheduling Conference Statement.

Very truly yours,

Robert Field
Assistant Attorney General

Enclosures
cc: Honorable Nelson W. Rupp, Jr. (with enclosures).

STATE OF MARYLAND,
DEPARTMENT OF THE
ENVIRONMENT

Plaintiff/Counter-Defendant

v.

NEUTRON PRODUCTS INC.

Defendant/Counter-Plaintiff

* IN THE
* CIRCUIT COURT
* FOR
* MONTGOMERY COUNTY,
* MARYLAND
* Civil No. 199036
* Honorable Nelson W. Rupp, Jr.

* * * * *

SCHEDULING CONFERENCE STATEMENT

Pursuant to the Scheduling Order of July 21, 1999, Plaintiff/Counter Defendant, the State of Maryland, Department of the Environment ("MDE") submits the following Scheduling Conference Statement. This statement is submitted based upon the assumption that MDE's Motion for Partial Summary Judgment filed on August 24, 1999, is granted in full leaving only the issue of the scope of relief for trial. If the Plaintiff's Motion for Partial Summary Judgment is denied in whole or in part, Plaintiff will file a supplemental statement within 30 days addressing any additional issues which are not addressed herein.

- a) For the Plaintiff, a brief statement of the nature of the controversy and the claims being made by the Plaintiff.

Defendant Neutron Products Inc. ("Neutron") is a licensee of the State of Maryland, Department of Environment ("Department") for certain operations conducted at its Dickerson, Maryland plant under license No. Md-31-025-01 ("01 license"). COMAR 26.12.01.01 Section C.29 ("Section C.29") requires that licensees who are authorized to possess the kinds and amounts of radioactive material permitted under the 01 license must

provide financial assurance in the amount of \$750,000 on or before October 15, 1998. Under Section C.29(g)(2), if this assurance is not provided within 180 days of its due date, Neutron loses its rights to receive, possess, store or ship radioactive material under the 01 license. Neutron has not submitted the requested financial assurance, but has responded with a series of legal attacks on the regulations, all of which are discussed at length in Plaintiff's Motion for Partial Summary Judgment. Since summary judgment is likely to be entered and the scope and validity of the regulations are purely legal questions, the only factual issue that should remain for trial is the scope of injunctive relief that the court should enter.

(b) for the [Counter] Defendant a concise statement of the [Counter] Defendant's defense.

Plaintiff/Counter Defendant maintains that, as a matter of law, each of counts I-V of Defendant/Counter Plaintiff's counter complaint are contrary to the law, request relief barred by Maryland law, do not state a cause of action recognized by Maryland law, or are barred by sovereign immunity. Plaintiff/Counter Defendant has filed a Motion for Partial Summary Judgment detailing its position and requesting summary judgment on the Counter Complaint. In any case, Plaintiff/Counter Defendant maintains that each of the Counts I-V in Counter Plaintiff's Complaint present purely legal questions for decision by this court.

(c) an itemization of damages or other relief sought for the Plaintiff and an itemization of matters in mitigation of damages or in opposition to the relief sought by the Defendant.

Plaintiff, at this time, does not seek damages or penalties. It seeks a decision

finding Neutron in violation of valid and enforceable regulations and an injunction ordering Neutron to cease operations under the 01 license and to provide a decommissioning plan.

The plan should provide that Neutron utilize its available resources and a portion of its income from its operations under other licenses at the site to fund the decommissioning of the facilities operated under the 01 license. Details of the decommissioning plan should be based upon agreement of the parties or upon the record developed in discovery and at trial. The State's opposition to the relief sought in the Counter-Complaint is contained in its Motion for Partial Summary Judgment.

- (d) the maximum offer or minimum demand now acceptable to your client.**

The State, at this time, is not requesting monetary penalties. The minimum acceptable injunction would be a prohibition of further operations under the 01 license, a selling of all assets related only to the 01 operations, the submission of an acceptable decommissioning plan which would be funded by the sale of existing assets and a commitment of a certain percentage of the gross income from the continuing operations of Neutron to the costs of decommissioning. The State makes no offer to resolve the Counter-Complaint.

- (e) A concise statement of the number of witnesses and a designation of the number and identity of proposed expert witnesses.**

Based upon the assumption that summary judgment will be granted on behalf of the State on Neutron's Counter-Complaint, Plaintiff plans to call sixteen witnesses. Witnesses to be used as expert witnesses are described below:

1. Roland Fletcher, Md. Department of Environment (factual and expert);
2. Ray Manley, Md. Department of Environment (factual and expert);
3. Alan Jacobson, Md. Department of Environment (factual and expert);
4. William Balanger, United States Environmental Protection Agency, Philadelphia, PA (expert);
5. Expert witnesses from Kaiser ICF, Fairfax, VA.:
 - a. John R. Collier;
 - b. Daniel Irwin Shain;
5. Expert witnesses from Arthur Andersen, Washington, D.C.:
 - a. John Wills;
 - b. Gary M. Rodrigues;
 - c. Rodney J. Bosco;
 - d. Desmond W. Chan, Ph.D.

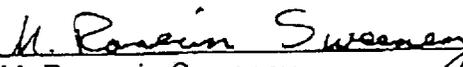
The State expects to utilize either Kaiser ICF or Arthur Andersen as a consultant and will, within the next thirty days, designate which of the listed witnesses it will be relying upon.

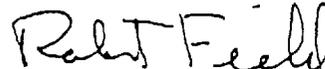
- (f) an estimation of the amount of time it will take to complete each party's portion of the trial.

The State estimates it will take seven days to present its case.

Respectfully submitted,

J. JOSEPH CURRAN, JR.
ATTORNEY GENERAL OF MARYLAND


M. Rosewin Sweeney



Robert Field
Assistant Attorneys General
Maryland Department of the Environment
2500 Broening Highway
Baltimore, Maryland 21224
(410) 631-3053

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of April, 1999, a copy of the Scheduling Conference Statement was mailed first-class mail, postage prepaid, to James Dalrymple, Esquire, 4 Professional Drive, Suite 118, Gathersburg, MD 20879-3424. Telephone 301-527-0117.


Robert Field
Assistant Attorney General

