

JAN -4 1994

Roland G. Fletcher, Administrator
Radiological Health Program
Maryland Department of the Environment
2500 Broening Highway
Baltimore, MD 21224

Dear Mr. Fletcher:

This responds to your April 28 and September 8, 1993 letters to Ms. T. H. Darden and Mr. C. Gordon, respectively, which included several questions related to the uncontrolled release of radioactive materials to the environment. These issues relate to the ongoing efforts of your Department relative to operations by Neutron Products, Inc. (NPI).

The recent inspection at NPI by the State of Maryland, with assistance by the NRC staff, focussed on this same issue of uncontrolled releases of radioactive materials to the environment. The results of that inspection and the answers to the specific questions which you asked (enclosed), should help to clarify these issues.

Please let me know if you wish to discuss these matters further.

Sincerely,
Original Signed By
RICHARD L. BANGART
Richard L. Bangart, Director
Office of State Programs

Enclosures:

1. Answers to Questions
2. Nuclear Pharmacy, Inc. Order
3. Listing of violations

Distribution

SA RF
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 RBangart, OSP
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 FCameron, OGC
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RI
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 12/28/93 E-Mail

*See previous concurrence.

OFC	NMSS	NMSS	OE:D	OGC	OSP: <i>RLB</i>		
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ENCLOSURE 1

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Roland G. Fletcher, Administrator
 Radiological Health Program
 Maryland Department of the Environment
 2500 Broening Highway
 Baltimore, MD 21224

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with
 Revision



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

January 4, 1994

Roland G. Fletcher, Administrator
Radiological Health Program
Maryland Department of the Environment
2500 Broening Highway
Baltimore, MD 21224

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ENCLOSURE 1

1. Question: Is there an acceptable criteria allowing for uncontrolled release of radioactive material? Is the regulatory limit for uncontrolled release from a licensee's facility zero?

Answer: The basic concept regarding releases which is set forth in 10 CFR Part 20 is that the licensee will have a program for controlling releases from its facility. Section 20.106 provides the limits for release of radioactive materials in effluents to unrestricted areas through airborne and liquid pathways, while 20.303 provides for disposal to the sanitary sewer system. Section 20.201 requires the licensee to evaluate releases to assure the above standards are met. Part 20 does not use the term "uncontrolled release," and therefore has no specific limit related to this term. However, Section 20.201 also requires evaluations which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. It is recognized that depending on a particular licensee operation, there may be some radioactive material which leaves the confines of a restricted area through pathways which are not continuously monitored. These pathways should not be definable air or water effluent or waste streams, but would more likely be in the form of contamination, spread through tracking or minor leakage from enclosed systems. These must be evaluated on their own merits relative to the requirements of Part 20, good health physics practices, potential safety significance, and criteria for unrestricted use of buildings and areas.

2. Question: If the answer to the above question is zero, please give benchmark examples of NRC licensee problems and remedial actions taken by NRC. Why are the above concepts not more clearly stated in the regulations?

Answer: While the regulations clearly spell out the requirements for the licensee to control releases through waste streams from its facility, they do not address all of the potential isotopes, compounds and uses that may need to be addressed as related to the matter of contamination that is inadvertently released off site. These types of issues are normally addressed in the licensing process. For example, licensees which have the potential for uncontrolled releases are requested to evaluate these in their license application. Typically, we would obtain from such licensees a commitment in their application to perform surveys, as necessary, and we would then incorporate such a commitment into the license through the use of a "tie down" condition.

3. Question: Has NRC had any history of radioactive material licensees releasing high specific activity windborne particles into residential communities? If so what action has been pursued when located particle activity is below maximum permissible concentrations listed in Regulatory Guides.

Answer: As a matter of clarification, the NRC does not have regulatory guides which address discrete particle contamination. We have had

instances of radioactive materials found in residential communities, although not necessarily involving high specific activity particles. In such cases, we have conducted surveys to determine the extent of the contamination, and evaluated the results to determine safety significance, and to compare the quantities found to the values for exempt concentrations and exempt quantities as found in the regulations, and also to guidance documents or branch technical positions for cleanup of material for unrestricted use. This evaluation is used to determine whether removal of the contamination is warranted.

4. Question: Is it an acceptable regulatory practice for a licensee to only monitor facility releases by residential environmental sampling? If no, why not?

Answer: No. The regulations require that the licensee must evaluate the concentration of effluents released from its restricted area. (See answer to question No. 1.) Environmental samples are not sufficient to quantify the concentrations of material released. Environmental sampling may be a part of an overall evaluation of material released, but cannot replace the requirement to evaluate the concentrations of materials released from the restricted area in effluent streams or other pathways.

5. Question: NPI's hot cell ventilation system which is situated above the facility's restricted area, discharges effluent into the air. Is this air restricted or unrestricted?

Answer: Air, by itself, is not restricted or unrestricted. The regulations define a restricted area as "...any area access to which is controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials." (See 20.3(a)(14)). Airborne radioactive material released to an unrestricted area must meet the concentration limits in 20.106. While the limits apply at the boundary of the restricted area, they are normally measured at the point of release from a vent or stack.

6. Question: Are there any NRC licensing examples where a 500 mRem per year facility boundary dose has been mandated?

Answer: We are not aware of any examples where this limit has been mandated in a license condition. However, during the evaluation of license applications and during the conduct of routine inspections, an evaluation is made of the radiation levels in unrestricted areas. In addition to reviewing the actual dose rates, evaluations are made to determine the likelihood of exposure to any individual in an unrestricted area of greater than 500 mr in any one year. This latter value is implicit in the provisions of 20.105(a).

7. Question: Please give examples of NRC mandates involving the requirement that independent technical consultants be hired by licensees, and how much review and revision are allowed by the

licensee's management prior to reports being submitted to the NRC?

Answer: In cases where the NRC has mandated the involvement of an independent technical consultant, such consultant is normally required to send its reports directly to the NRC at the same time that they are sent to the licensee. Licensee management is not allowed to review and revise the report itself prior to its issuance to the NRC. The licensee may, of course, provide their own analysis and conclusions under separate cover to the NRC. The attached Order issued to Nuclear Pharmacy, Inc. is typical of how this requirement has been imposed.

8. Question: Please give examples of penalties levied against licensees who:

- a. violate license amendments, and/or
- b. cannot control radioisotope release, and/or
- c. fail to ship radioactive wastes at a prescribed rate and store low-level radioactive waste in unrestricted areas.

Answer: We understand part a. of the question to refer to license conditions. Many NRC Notices of Violation (NOV's) cite license conditions, and examples can be found in NUREG-0940, Enforcement Actions, Significant Actions Resolved. Copies of this document are routinely distributed to the Agreement States. With regard to parts b. and c. of the question, a word search of files resulted in the listing which is shown in the Enclosure. The references are to various volumes of NUREG-0940. Please note that the dollar amounts for the civil penalties are not specifically assessed for the subject violation, since these cases involve several violations. Detailed information on how the NRC addresses violations and assigns civil penalties is found in the Enforcement Policy (10 CFR Part 2, Appendix C). The Supplements to the Policy provide examples of various violations and the severity levels that are assigned to those violations.

9. Question: NPI's MD-31-025-01 radioactive material license has been in "timely renewal" since 1980. During this period, there has been a myriad of correspondence between this agency and NPI to resolve differences. The license has been complete for over a year, but is "hostage" to the civil action. Is there any NRC action on record that supports withholding a license renewal until the completion of legal action?

Answer: There are no NRC procedures or requirements which prohibit the issuance of a license renewal while legal action is being carried out against a licensee. We have not undertaken a file review to see if we have had any cases of this type. The actions taken and the timing of such action would have to be evaluated on the merits of the particular case.



MARYLAND DEPARTMENT OF THE ENVIRONMENT

2500 Broening Highway • Baltimore, Maryland 21224

(410) 631-3000

William Donald Schaefer
Governor

David A.C. Carroll
Secretary

September 8, 1993

Mr. Craig Gordon, Regional State Agreements Officer
United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia PA 19406

RE: Request for Technical Assistance

Dear Mr. Gordon:

This letter refers to the August 4, 1992 meeting between the Maryland Department of the Environment's (MDE) Radiological Health Program (RHP) and the United States Nuclear Regulatory Commission (USNRC) regarding USNRC radiation safety concerns about Neutron Products Inc. (NPI). As a result of these discussions, it was determined that our two agencies would work together under a team concept to identify solutions to radiation safety concerns at NPI. It was further determined that, upon a MDE written request, USNRC could provide technical assistance in the following areas:

- A. Uncontrolled release of cobalt-60 from the NPI facility.
- B. Radioactive material waste management practices at NPI.
- C. Decommissioning of NPI.

This letter also refers to the RHP's letter to the USNRC dated August 6, 1992 outlining concerns regarding the mechanism of uncontrolled release of radioactive material occurring at NPI (letter attached).

Due to the upcoming civil action against NPI, the Maryland Attorney Generals office cannot, at this time, implement additional legal actions to require NPI to obtain the services of a private consultant to review and analyze these problems. At RHP's request NPI are themselves conducting an ongoing and open ended evaluation.

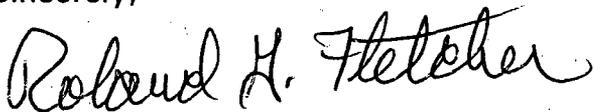
Mr. Craig Gordon
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RHP will be conducting an inspection of NPI on October 13-15, 1993. The RHP team will consist of Messrs. Trump, Manley, Jacobson, and Nelson. Pursuant to the above cooperative effort between USNRC and RHP, onsite advisory and technical assistance could be rendered by USNRC in the following areas:

- 1) Assist RHP in an overview inspection of NPI to evaluate compliance status in regard to those concerns listed on the August 6, 1992 letter.
- 2) Assist RHP in an overview analysis of NPI's capabilities to adequately evaluate the concerns of the August 6, 1992 letter.
- 3) Assist RHP in an evaluation of NPI's capabilities to facilitate remedial actions to any determined insufficiencies.

The RHP staff greatly appreciates the time, assistance, and expertise you bring to the above matters. Should you have any questions regarding this letter, please contact Mr. Raymond Manley or me at (410) 631-3301, and we will be pleased to discuss them with you.

Sincerely,



Roland G. Fletcher, Administrator
Radiological Health Program

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RGF/REM/dpn