UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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| In the Matter of | ) | |
| Nuclear Pharmacy, Incorporated | ) | Byproduct Material License |
| 319 West Ontario Street | ) | No. 12-18044-01MD |
| Chicago, Illinois 60610 | ) | EA-80-33 |

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

Nuclear Pharmacy, Incorporated, Chicago, Illinois (the "licensee") is the holder of Byproduct Material License No. 12-18044-01MD (the "license") issued by the Nuclear Regulatory Commission ("the Commission") which authorizes the licensee to process, mix or compound, and distribute prepared radiopharmaceuticals containing byproduct material to authorized recipients as well as produce technetium 99m pertechnetate and indium 113m chloride from generators. The license was issued on April 20, 1978, and will expire on April 30, 1983.

II

On January 22 and February 27, 28 and 29, 1980, an inspection was conducted of licensed activities under the license. As a result of this inspection it appears that the licensee has not conducted its activities in full compliance with the conditions of the license and with the requirements of the Nuclear Regulatory Commission's "Standards for Protection Against Radiation," Part 20, Title 10, Code of Federal Regulations. A written Notice of Violation was served upon the licensee by letter dated June 27, 1980, specifying the items of noncompliance in

accordance with 10 CFR 2.201. A Notice of Proposed Imposition of Civil Penalties in the amount of Five Thousand Seven Hundred Dollars was served concurrently upon the licensee in accordance with Section 234 of the Atomic Energy Act of 1954, as amended (42 USC 2282) and 10 CFR 2.205, incorporating by reference the Notice of Violation which stated the nature of the items of noncompliance, and the provisions of the NRC regulations and license conditions with which the licensee was in noncompliance. Answers from the licensee to the Notice of Violation and to the Notice of Proposed Imposition of Civil Penalties were dated July 22, 1980. Along with its response, the licensee paid the full civil penalty proposed for items 1, 3, 5, 6, 7 and 8, and one half the civil penalty proposed for item 4. The licensee denied item 2 and did not pay the proposed civil penalty for this item.

III

After consideration of the answers received and the statements of fact, explanation, and argument for mitigation or cancellation of items 2 and 4 of the Notice of Violation contained therein, as set forth in Appendix A to this Order, the Director of the Office of Inspection and Enforcement has determined that the full penalties proposed for items 2 and 4 in the Notice of Violation should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (42 USC 2282) and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The licensee pay civil penalties in the total amount of One Thousand Five Hundred Dollars within twenty-five days of the date of this Order, by check, draft, or money order payable to the Treasurer of the United States and mailed to the Director of the Office of Inspection and Enforcement.

V

The licensee may, within twenty-five days of the date of this Order, request a hearing. A request for a hearing shall be addressed to the Secretary to the Commission, U.S.N.R.C., Washington, D.C. 20555. A copy of the hearing request shall also be sent to the Executive Legal Director, U.S.N.R.C., Washington, D.C. 20555. If a hearing is requested, the Commission will issue an Order designating the time and place of hearing. Upon failure of the licensee to request a hearing within twenty-five (25) days of the date of this Order, the provisions of this Order shall be effective without further proceedings and, if payment had not been made by that time, the matter may be referred to the Attorney General for collection.

VI

In the event the licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) whether the licensee was in noncompliance with the Commission's requirements as set forth in items 2 and 4 of the Notice of Violation referenced in Sections II and III above; and,

(b) whether on the basis of such items of noncompliance, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Victor Stello, Jr.
Director
Office of Inspection
and Enforcement

Dated at Bethesda, Maryland
this 10th day of November, 1980

Attachment:
Appendix A, Evaluation
and Conclusions

## APPENDIX A

## EVALUATION AND CONCLUSIONS

A Notice of Violation was issued to the licensee on June 27, 1980. That Notice identified four separate infractions and seven deficiencies resulting from noncompliance with various Commission requirements. The licensee admitted nine of the eleven alleged items of noncompliance; it denied one alleged infraction (item 2) and while admitting another (item 4) requested mitigation of the civil penalty from $1,000 to $500.

For each contested item of noncompliance and associated civil penalty identified in the Notice of Violation (dated June 27, 1980), the original item of noncompliance is restated and the Office of Inspection and Enforcement's evaluation and conclusion regarding the licensee's response to each item (dated July 22, 1980) is presented.

### Item 2

### Statement of Noncompliance

10 CFR 20.101(a) limits the extremity dose of an individual in a restricted area to 18.75 rems per calendar quarter.

Contrary to the above, an individual working in the restricted area received an extremity dose of 21.8 rems during the 4th calendar quarter of 1979.

This is an infraction. (Civil Penalty - $1,000)

### Evaluation Licensee Response

Although the licensee admits that an individual working in a restricted area received a dose in excess of that permitted by 10 CFR 20.101(a), it denies that it has committed any infraction of the regulations since the management of the licensee was not at fault in that it did not cause the overexposure of its employee. The licensee states that pursuant to the terms of the cited regulation, it has not committed an infraction unless the overexposure is caused by the licensee's negligence. The licensee also argues that the level of exposure to the individual involved may have been lower than the dosimetry reading reflected, because the individual used contaminated fingers to remove his ring badge. Finally, it argues that even if the exposure reading of 21.8 rems were correct (as compared to the dose limit in the regulation of 18.75 rems) the overexposure was not impermissible under 10 CFR 20.101(a) unless it was caused by the manner in which the licensee possessed, used or transferred the material.

These arguments of the licensee are not well taken for several reasons. First, we do not agree that the licensee had no role in causing the overexposure to the individual involved; the manner of the licensee's handling of material (through its employee) did cause the exposure. The basic elements of radiation protection involve time, distance, and shielding, all matters under the licensee's control. The licensee chose the type and quantity of isotopes to be used, established the

procedures and selected the equipment to be used, and supervised the program. Further, the licensee could have prevented the overexposure by decreasing the exposure time. The inspection report shows that the licensee had not been keeping a careful watch over dosimeter reports. In fact the licensee failed to develop procedures which would call for less exposure time, and safer handling of radioactive materials. This resulted in an employee receiving an overexposure.

The licensee does not claim that any other source of radiation caused the reading shown on the dosimeter; licensed material and no other radiation source caused an exposure to the hand of an individual in excess of the limits in 10 CFR 20.101(a).

Secondly, the licensee's characterization of the question involved as being whether it was negligent with regard to the overexposure incident is not correct. The Commission has already determined In the Matter of Atlantic Research Corporation, CLI-80-7, 11 NRC 413 (1980), that its authority to impose civil penalties upon a licensee pursuant to section 234 of the Atomic Energy Act is not limited to situations in which management negligence contributed to the license violation.

As in Atlantic Research, the licensee's argument here amounts to an assertion that it should not be penalized because no specific action by its management caused the commission of the infraction for which it has been cited. The Commission emphatically rejected that line of reasoning in Atlantic Research:

> "Under that approach, the responsibility for infractions of license provisions or Commission regulations would be divided between the licensee's management and its employees. We believe that this would be an unsound enforcement policy because management's freedom from culpability could be interpreted as freedom from responsibility. In the worst case, this might lead to a situation where a licensee may choose a course which minimizes the potential for culpability even though some alternative would better protect public health and safety. We find that such a division of responsibility between a licensee and its employees has no place in the NRC regulatory regime which is designed to implement our obligation to provide adequate protection to the health and safety of the public in the commercial nuclear field. In general, we believe a strong enforcement policy dictates that the licensee be held accountable for all violations committed by its employees in the conduct of the licensed activity." 11 NRC at 421-22. (Emphasis added.)

The Commission emphasized in that decision that as long as (1) a violation has been established (2) the proposed civil penalty may positively affect the conduct either of the licensee or any other person and (3) the civil penalty is not grossly disproportionate to the gravity of the offense, the Commission has discretion to impose the civil penalty as a sanction for the infraction or violation. 11 NRC at 420-421. Thus, regardless of whether NPI caused the overexposure incident or was negligent in failing to prevent it, there is no question that it should be held accountable for this infraction and that the three prerequisites for imposition of a civil penalty are present.

With regard to the licensee's argument that the amount of the overexposure is not impermissible pursuant to 10 CFR 20.101(a) unless it caused the overexposure, that regulation imposes an absolute limit on exposures; exceeding the dose limit is flatly prohibited. In addition, 10 CFR 20.1(b) clearly states that the purpose of Part 20 is to control the use of licensed material by any licensee in such a manner that the total dose to any individual does not exceed the standards of radiation protection prescribed in the pertinent regulations. Further, with regard to the argument made by the licensee that the level of exposure to the individual may have been lower than the dosimetry reading, the inspection report indicates that although contamination may have caused some exposure of the badge, exposure from contamination would only be about 130 millirems of the 21,821 millirems recorded by the badge. Further, the inspection report showed that extremity exposures for individuals working in this facility could be high.

Finally, we note the licensee's description of the action taken after the overexposure and its report that this action has reduced exposures since the incident in question. Corrective action is always required; however, we believe that this action could have been taken prior to the time of the overexposure to minimize the possibility of its occurrence.

Conclusion

The licensee does not contest the fact that the overexposure noted in the Notice of Violation occurred. The information presented by the licensee does not provide a basis for modification of this enforcement action. This item as stated in the Notice of Violation is an item of noncompliance.

Item 4

Statement of Noncompliance

10 CFR 20.201(b) requires each licensee to make or cause to be made such surveys as may be necessary for him to comply with the regulations in this part. 10 CFR 20.106 limits the amount of licensed material that can be released to the unrestricted area.

Contrary to the above, during 1979 and as of February 29, 1980, the licensee had not made surveys to determine that the concentrations of iodine 131 released in airborne effluents from fume hoods in its facilities were within the limits set forth in 10 CFR 20.

This is an infraction. (Civil Penalty - $1,000)

Evaluation of Licensee Response

The licensee admits that its failure to conduct the required surveys constitutes an item of noncompliance. Its request for mitigation of the civil penalty is based upon the fact that at the time of the February 1980 NRC inspection, the equipment necessary to perform the surveys had been installed and the initial air sampling counts had already been taken. Although these counts had been

taken, the licensee candidly states that the equipment had not been calibrated and the data not evaluated to indicate how many counts constitute a microcurie or how many cc's of air passed through the filter during the sampling time. However, the licensee argues that the number of counts in the air samples was so low that it can be clearly concluded that releases of radioactive effluents were within acceptable limits. Finally, the licensee states that properly evaluated air sampling surveys are currently performed every week, and that it is now in full compliance with 10 CFR 20.201(b).

The licensee has previously been cited for the identical item of noncompliance in a Notice of Violation dated April 5, 1979, arising from inspections performed by the NRC regional office on January 31 and February 2, 1979. In particular, item 5 of that Notice of Violation specified the following:

> 10 CFR 20.201(b) "Surveys," requires you to make such surveys as may be necessary for you to comply with all sections of Part 20.
>
> Contrary to this requirement, as of the date of this inspection, you failed to make such surveys as were necessary to assure compliance with 10 CFR 20.106, "Concentrations in effluents to unrestricted areas," a regulation that limits the yearly average concentration of iodine and xenon contained in the air discharged to the unrestricted area. Specifically, no evaluations were made of the concentration of iodine discharged from your Elmhurst facility.

In response to that Notice of Violation, the licensee stated, in an undated letter received by the NRC regional office on April 25, 1979, that:

> In regard to Item 5, the fume hood exhaust in our facilities are forced through a trap consisting of a filter/activated charcoal system prior to venting to an unrestricted area. The efficiency of the trapping system will be periodically evaluated by taking the wipe tests before and after the trapping device. From this data, the efficiency of the trap will be determined, and together with the activity utilized, an estimate of the radioactive release will be determined. The wipe tests will be performed on a monthly basis to constantly assess the trapping efficiency.

Further, the licensee stated that all items of noncompliance had been corrected and that the procedures had been or would be initiated by May 1, 1979. Thus, notwithstanding the licensee's observation in response to the current (June 27, 1980) Notice of Violation that it had installed the appropriate equipment for air surveys and taken initial sampling counts by the time of the February, 1980 inspection, the fact is that the equipment could have and should have been installed shortly after the April 5, 1979 Notice of Violation had been issued. Indeed, given the licensee' statement (in its undated April 1979 response to the first citation) that it had corrected the items of noncompliance and that the necessary procedures would be initiated by May 1, 1979, its argument for mitigation of the currently assessed civil penalty is particularly unpersuasive.

The licensee also requests mitigation based upon its conclusion that the number of counts in the air samples was so low that effluent releases could clearly be concluded to be within acceptable limits. However, based upon NRC regional office experience with other licensees who used similar amounts of iodine-131 and the frequency with which the licensee used liquid iodine-131 (about twice per month), the 10 CFR Section 20.106 limit could be exceeded under circumstances such as a spill in the hood or the receipt of an iodine-131 dose lacking the proper buffer to keep the iodine in solution.

Conclusion

The licensee does not contest the fact that it has committed an infraction. The information presented by the licensee, especially in view of the repetitive nature of the current citation, does not provide a basis for modification of this enforcement action. This item as stated in the Notice of Violation is an item of noncompliance.