



SPRING HOUSE, PA 19477-0776 (215)628-5000

September 28, 1989

Mr. John D. Kinneman, Chief
Nuclear Materials Safety Section B
Division of Radiation Safety & Safeguards
U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Dear Mr. Kinneman:

Re: Docket No. 030-6212
License Number: 37-09743-01
Routine Inspection Number 030-6212/89-001

During the course of the inspection referred to above, it was pointed out to the inspector, Mr. J. T. Jensen, that drums which contained liquid waste were checked for exterior contamination that could have arisen during the liquid transfer. It was also pointed out that other low level radioactive waste was transferred in closed plastic bags into drums for disposal. These drums were not routinely checked for removable contamination.

At the conclusion of the inspection, the findings were discussed with our Radiation Safety Officer, Brian E. Reynolds, Ph.D., C.I.H.; however, no mention was made at that time of a violation of NRC requirements.

In order to correct the situation, and to prevent recurrence:

- 1) All drums containing radioactive waste are being surveyed prior to shipment and the results of the surveys are being filed with the shipping manifests.
- 2) Operating procedures have been revised to require such surveys to be carried out. These revised procedures are attached.
- 3) The process was started with a September 20, 1989 shipment of radioactive waste.

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37-09743-01

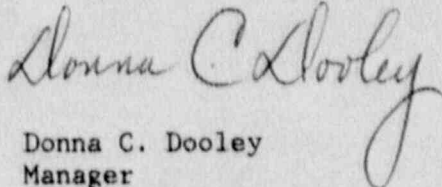
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Mr. John D. Kinneman, Chief
Nuclear Materials Safety Section B.
U. S. Nuclear Regulatory Commission

September 28, 1989

By taking these steps, I believe McNeil Pharmaceutical has achieved full compliance with NRC requirements.

Sincerely,

A handwritten signature in cursive script that reads "Donna C. Dooley". The signature is written in dark ink and is positioned above the typed name and title.

Donna C. Dooley
Manager
Industrial Hygiene & Safety

DCD:ma

RADIOACTIVE WASTE PACKAGING PROCEDURES

Radioactive waste will be packaged for shipment under the supervision of the Radiation Safety Officer.

Respiratory protection is required when PERLITE is being handled.

1. Scintillation Vials

To be packaged according to the procedures outlined in the latest information from Teledyne Isotopes.
PERLITE is an acceptable absorbent.

2. Large Volume Liquids

Water solutions only are to be accepted. If the disposal slip either does not identify the solvent, or if the solvent contains anything other than water, notify the Radiation Safety Officer at Extension 5858.

Package according to the Teledyne instructions, placing ten (10) gallons in each 30 gallon inner drum. Seal the inner drum, place top on 55-gallon overpack drum, and place slips on top of drum.

3. Radioactive Waste from the Radiosynthesis Laboratory

This drum is sealed before it is removed from the Radiosynthesis Laboratory. No additional materials will be added to this drum.

4. Dry Radioactive Waste

This waste is collected in five (5) gallon pails in the laboratories. When the pail is picked up, ensure that:

- the plastic bag is tied shut
- there is a tag on the can indicating the radioisotope and amount. Do **NOT** accept any cans without this label.
- o Line a 55-gallon drum with a plastic liner. Put several inches of PERLITE in the bottom of the drum. Place the drum in the compactor.
- o Remove the slip from the pail, and place it in the plastic sleeve on the compactor.
- o Place the unopened bag from the 5-gallon pail in the 55-gallon drum that is in the compactor.
- o Fill the drum at least half full before compacting the contents.

Radioactive Waste Packaging Procedures

4. Dry Radioactive Waste (Cont'd)

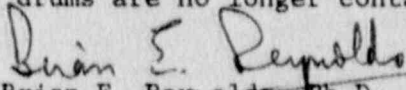
- o Compact the materials twice.
- o Continue adding the bags of waste to the drum, compacting after two or three bags have been added.
- o When the drum is full, add PERLITE as absorbent.
- o Tie off the plastic liner before removing the drum from the compactor.
- o Put the lid on the drum, remove the slips from the plastic sleeve and place on the top of the drum.

If a partially filled drum is left in the compactor, leave the compactor press in the down position.

5. Shipment

Prior to shipment of all radioactive waste the following steps will be taken:

- o Amounts of radioactivity in each drum will be totalled from the slips, and will be written on the top of the drum. The information will include isotope and millicurie amount.
- o Slips will be collected, and attached to the shipping manifest.
- o The Radiation Safety Officer will conduct a smear survey on all filled radioactive waste drums prior to their removal from the storage area. The results will be attached to the shipping manifest.
- o Drums that have surface contamination above the McNeil action level of 100 disintegrations per minute above background per 100 sq. cm. will be decontaminated using appropriate procedures. These drums will be resurveyed. The decontamination procedure will continue until the smear survey indicates that the drums are no longer contaminated.


Brian E. Reynolds, Ph.D., C.I.H.
Radiation Safety Officer



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

Suspense

SEP 08 1989

Docket No. 030-06212

License No. 37-09743-01

McNeil Pharmaceutical
ATTN: Ms. Donna Dooley
Manager of Industrial Hygiene and Safety
Welsh and McKean Roads
Spring House, Pennsylvania 19477-0776

Gentlemen:

Subject: Routine Inspection No. 030-06212/89-001

On August 17, 1989, John T. Jensen of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with Brian E. Reynolds, Ph.D. at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed as Appendix A and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

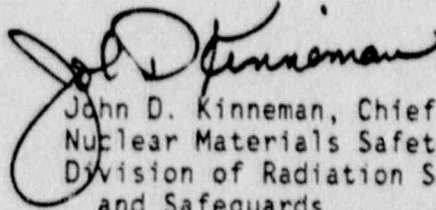
In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

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Your cooperation with us is appreciated.

Sincerely,

A handwritten signature in black ink, appearing to read "John D. Kinneman". The signature is written in a cursive style with a large, looping initial "J".

John D. Kinneman, Chief
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards

Enclosure:
Appendix A, Notice of Violation

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania
Brian E. Reynolds, Ph.D., Radiation Safety Officer

APPENDIX A
NOTICE OF VIOLATION

McNeil Pharmaceutical
Spring House, Pennsylvania 19477-0776

Docket No. 030-06212
License No. 37-09443-01

As a result of the inspection conducted on August 17, 1989, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1988), the following violation was identified.

10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their plants or deliver licensed material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Part 170-189.

49 CFR 173.475(i) requires that, prior to each shipment of any package, the shipper must insure by examination or appropriate test that the external radiation and contamination levels are within allowable limits.

Contrary to the above, as of August 17, 1989, 55-gallon drums containing radioactive waste (approximately five shipments of 10 drums were made each year) were not tested for removable contamination.

This is a Severity Level IV violation. (Supplement V)

Pursuant to the provisions of 10 CFR 2.201, McNeil Pharmaceutical is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

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