



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Health Services Administration

Occupational Health and Safety
Management Branch

June 1, 1989

Navajo Area
Indian Health Service
P. O. Box G
Window Rock, Arizona 86515

United States Regulatory Commission
Washington, D.C. 20555

Attention: Document Control Desk

Subject: Reply to Notice of Violation Docket No. 030-10696
License No. 02-16270-01

Gentlemen:

This response is directed in reference to the routine safety inspection conducted by Mr. J.F. Pang, Region V on February 9, 10, and 16, 1989, and the resultant "Notice of Violation" (attachment 1) issued by Mr. Robert J. Pate, Chief, MMSSB, Region V.

This office was unable to respond to this matter in a timely manner pursuant to the provisions of 10 CFR 2.201 due to an untimely and circuitous routing of the notice. The original Notice of Violation has never been received by the Office of the Area Director, NAIHS. A photocopy of the Notice of Violation was sent from the Phoenix Area to Headquarters in Rockville to us. This situation was brought to Mr. Pang's attention as well as the need for extending the response time.

Violation A properly indicates that contrary to Item 12 of the license application, the licensee has failed to provide self-reading radiation dosimeters (pocket ionization chambers) to the operators upon acquisition of the gauge. The Indian Health Service, Navajo Area Office, has, as of January 3, 1989, employed a health physicist, myself who in addition to other duties will be responsible as the Radiation Safety Officer (RSO) for the license. Regarding the specific violation, it is my opinion that the use of pocket ionization chambers is not an effective means of monitoring operator exposures. The conditions and situations under which the gauge is used and the sensitivity of the above dosimetry devices to rough handling and abuse make their use inappropriate. Additionally, there is a need to monitor multiple users during any given period as well as the need to obtain timely estimates of user exposures. It is herein proposed that the requirement for personnel dosimetry be modified to include the use of individual real-time, digital dosimeters capable of retaining accumulated exposure in memory. The change in the designated RSO, as well as the use of alternative methods of dosimetry, will be provided for via an application for amendment to the license.

Violation B properly indicates the licensee's failure to annually calibrate the radiation detection instruments itemized under Item 10 of the license application. While the instruments in question were available and operational at the time of inspection, they had not been calibrated as per Item 11.

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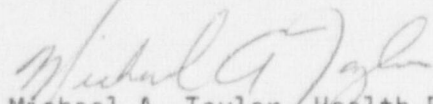
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While there may be a need for radiation detection instrumentation in the event of an emergency situation, it is felt that the need for critically calibrated instrumentation is unnecessary, and that in-house verification of instrument function with the use of appropriate check sources would provide the necessary degree of safety. Given the nature of the source material in question, (special form, sealed capsules), critical evaluations via the use of certified leak tests would continue to be the procedure of choice. A request will be made to amend our license accordingly. Arrangements are currently being made to have the instruments listed in Item 10 inspected and calibrated as per the license application.

Violation C.1 concerning the lack of proper DOT documentation has been addressed and the proper documents have been obtained from the guage manufacturer (attachment 2). Violation C.2 has also been addressed and the proper documentation and procedures have been implemented in order to ensure compliance with all applicable regulations (attachment 3).

I would like to express our appreciation for Mr. Pang's assistance in this matter and his critical and professional evaluation of our overall operation. It is our desire to address and appropriately respond to each of the situations brought to our attention by Mr. Pang's recent visit. If you should have any questions or comments regarding our response, please feel free to contact me directly at (602) 871-1396 or FTS# 572-8251.

Sincerely,



Michael A. Taylor, Health Physicist
OHSBM, OEHE, NAIHS, USPHS

xc: Regional Administrator, Region V
Michel Lincoln, Area Director, NAIHS
Charles O. Dowell, P.E., Director, OEHE, NAIHS
Richard Haskins, Chief, OHSMB, OEHE, NAIHS



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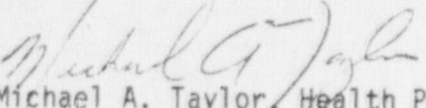
Violation B properly indicates the licensee's failure to annually calibrate the radiation detection instruments itemized under Item 10 of the license application. While the instruments in question were available and operational at the time of inspection, they had not been calibrated as per Item 11.

While there may be a need for radiation detection instrumentation in the event of an emergency situation, it is felt that the need for critically calibrated instrumentation is unnecessary, and that in-house verification of instrument function with the use of appropriate check sources would provide the necessary degree of safety. Given the nature of the source material in question, (special form, sealed capsules), critical evaluations via the use of certified leak tests would continue to be the procedure of choice. A request will be made to amend our license accordingly. Arrangements are currently being made to have the instruments listed in Item 10 inspected and calibrated as per the license application.

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Violation A properly indicates that contrary to Item 12 of the license application, the licensee has failed to provide self-reading radiation dosimeters (pocket ionization chambers) to the operators upon acquisition of the gauge. The Indian Health Service, Navajo Area Office, has, as of January 3, 1989, employed a health physicist, myself who in addition to other duties will be responsible as the Radiation Safety Officer (RSO) for the license. Regarding the specific violation, it is my opinion that the use of pocket ionization chambers is not an effective means of monitoring operator exposures. The conditions and situations under which the gauge is used and the sensitivity of the above dosimetry devices to rough handling and abuse make their use inappropriate. Additionally, there is a need to monitor multiple users during any given period as well as the need to obtain timely estimates of user exposures. It is herein proposed that the requirement for personnel dosimetry be modified to include the use of individual real-time, digital dosimeters capable of retaining accumulated exposure in memory. The change in the designated RSO, as well as the use of alternative methods of dosimetry, will be provided for via an application for amendment to the license.

Violation B properly indicates the licensee's failure to annually calibrate the radiation detection instruments itemized under Item 10 of the license application. While the instruments in question were available and operational at the time of inspection, they had not been calibrated as per Item 11.

APPENDIX A

NOTICE OF VIOLATION

Department of Health and Human Services
Navajo Area, Indian Health Service
P. O. Box G
Window Rock, Arizona 86515

Docket No. 030-10696
License No. 02-16270-01

During an NRC inspection conducted on February 9, 10 and 16, 1989 certain violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1988), the violations are listed below:

License Condition 18 requires, in part, that except as specifically provided otherwise by this license, the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in application dated August 22, 1979.

- A. Item 12 of the application provides that self reading radiation dosimeter (pocket ionization chamber) will be issued to a operator upon acquisition of the gauge, and readings taken will be recorded upon return of the gauge.

Contrary to the above requirement, at the time of the inspection, pocket dosimeters (or any other personnel monitoring devices) were not being used by the operators of the gauge.

This is a Severity Level IV Violation (Supplement VI).

- B. Item 10 of the application provides that portable survey instruments will be maintained for monitoring and surveys. Item 11 of the application also provides that these instruments will be calibrated annually.

Contrary to the above requirement, at the time of the inspection, the available survey instruments had not been calibrated since August 22, 1985.

This is a Severity Level IV Violation (Supplement VI).

- C. License Condition 17 provides, in part, that the license may transport licensed material in accordance with 10 CFR 71. 10 CFR 71.5 states, in part, "Each licensee who transports licensed material outside the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the regulations appropriate to the mode of Transport of DOT in 49 CFR 170 through 189."

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1. 49 CFR 173.415(a) provides, in part, that each shipper of a Specification 7A package must maintain on file at least one year after the latest shipment, and shall provide to DOT upon request, a complete documentation of tests and an engineering evaluation on comparative data showing that the construction methods, packaging design, and materials of construction comply with that specification.

Contrary to the above requirement, at the time of the inspection, the licensee did not have the documentation of the DOT 7A test results and evaluation for the DOT 7A shipping container used to transport the gauge.

This is a Severity Level V Violation (Supplement VI).

2. 49 CFR 177.817(a) requires, that a carrier may not transport a hazardous material unless it is accompanied by a shipping paper prepared in accordance with 49 CFR 172.200 thru 49 CFR 172.203. Also, 49 CFR 177.817(e) requires, in part, that the shipping papers be readily accessible, in the cab of the vehicle, within reach of the driver of the vehicle.

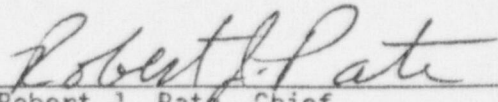
Contrary to the above requirements, at the time of the inspection, shipping papers were neither prepared nor used by the licensee when transporting the gauge to and from the temporary job sites.

This is a Severity Level V Violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Department of Health and Human Services is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region V within 30 days of the date of the letter transmitting this Notice. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation if admitted, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown.

FOR THE NUCLEAR REGULATORY COMMISSION

Dated at Walnut Creek, California
this 28th day of February 1989


Robert J. Pate, Chief
Nuclear Material Safety and
Safeguards Branch

SPECIAL FORM

attachment 2

173.39B(a)(Note 1) Each shipper of special form radioactive material shall maintain on file for at least one year after the last shipment, and be prepared to provide the DOT, a complete certification and safety analysis that the special form material meets the requirements.

173.39B(a) SPECIAL TESTS, Special form Material

- (1) FREE DROP -- Ten free falls of dummy capsule. No damage. Capsule experienced random tumble during fall striking at various angles upon contact. (capsule is further mounted within device and will not experience exposure to outside in event of similar free fall of actual finished device).
- (2) PERCUSSION -- Dummy capsule placed on 1/4" lead sheet on concrete. Steel rod allowed to slide down aluminum angle guide (top 1" off center) distance of 40". Five falls with weldment upright and five falls with weldment downwards. No damage.
- (3) HEATING -- Dummy capsule heated to red hot glow (1475 deg F) with torch. Maintained for 10 minutes. Discoloration but no damage to capsule integrity.
- (4) IMMERSION -- Dummy capsule placed in water breaker for 64 hours. No damage.

This is to certify that the encapsulated radioactive material in CPN's gauge has been tested for and is in compliance with the requirements for special form material. It has been issued IAEA Certificate of Competent Authority No. USA/D115/S by the US DOT.

William Mancuso
 CPN Corp.
 William Mancuso
 Radiation Safety Officer

July 1, 1985

PACKAGING

173.394(a)(1) Each shipper of a Specification 7A package must maintain on file for at least one year after the latest shipment, and be prepared to provide the DOT, a complete certification and supporting safety analysis demonstrating that the construction methods, packaging design, and material of construction are in compliance with the specifications.

CPN's gauges contain Radioactive Material in Special Form and as such must be packaged according to Specification 7A, Type A. The gauges are shipped in combination shipping and carrying cases made of high density polyethylene, fiberglass or aluminum.

173.39B(b) SPECIAL TESTS for a Type A package

- (i) WATER SPRAY -- Exempt. Package is of plastic or metal.
- (ii) FREE DROP -- Exempt. Package is of plastic or metal.
- (iii) CORNER DROP -- Exempt. Package is of plastic or metal.
- (iv) PENETRATION -- A steel rod 1.25 inches in diameter with hemispherical ends was dropped from a distance of 40 inches on to the center of the top of the case. No cracking or other significant deformation occurred.
- (v) COMPRESSION -- Five loaded cases were stacked on top of a sixth case for a period of 24 hours. No visible deformation was observed.

This is to certify that the shipping case for CPN's gauge has been tested for and is in compliance with the requirements for a Type 7A, Type A package.

The gauge was removed from the shipping case and subjected to the same tests. The gauge when transported, removed from the shipping case, is in compliance with the requirements for a Type 7A, Type A package, except for labeling.

William Mancuso
 CPN Corp.
 William Mancuso
 Radiation Safety Officer

July 1, 1985



Date May 12, 1989

Memorandum

From Health Physicist, NAIHS

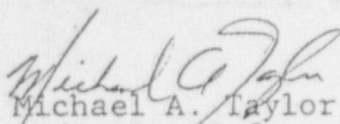
Subject Transportation Requirements for CPN Portaprobe Density/
Moisture Guage.

To Authorized Users of CPN Guage.

In order to comply with DOT Hazardous Material Regulations regarding transportation, specifically regulation 49 CFR 177.817, the "Shipping Paper" provided on the reverse must accompany the CPN D/M guage whenever it is transported via a motor vehicle.

Specific procedures are detailed below.

These procedures apply to private carrier, motor vehicle transport only! Transporation via any other mode or vehicle is not authorized or provided for by these shipping papers.


Michael A. Taylor
Radiation Safety Officer

177.817(e) Shipping Paper accessibility--accident or inspection. A driver of a motor vehicle containing hazardous material shall ensure that the shipping paper (describing the hazardous material) is readily available to, and recognizable by, authorities in the event of accident or inspection. Specifically the driver shall--

(1) Clearly distinguish the shipping paper, if it is carried with other papers of any kind, by either distinctively tabbing it or by having it appear first.

(2) Store the shipping paper as follows:

(i) When the driver is at the vehicle controls, the shipping paper must be: (A) Within his immediate reach while he is restrained by the lap belt; and (B) either readily visible to a person entering the driver's compartment or in a holder mounted to the inside of the door on the drivers side of the vehicle.

(ii) When the driver is not at the vehicle's controls, the shipping paper shall be: (A) In a holder which is mounted to the inside of the door on the drivers side of the vehicle; or (B) on the driver's seat in the vehicle.



Date May 12, 1989

Memorandum

From Health Physicist, NAIHS

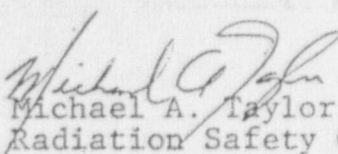
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SHIPPING PAPER

NAVAJO AREA INDIAN HEALTH SERVICE
ARIZONA HWY 264
ST. MICHAEL'S, ARIZONA 86511
(602) 871-5851, FTS #: 572-8251

One Case, RADIOACTIVE MATERIAL, SPECIAL FORM, N.O.S., 7, UN2974
Cs - 137, 10 mCi
Am - 241/Be, 50 mCi
RADIOACTIVE YELLOW - II Label
Transport Index 0.4
USA DOT 7A TYPE A Package
