

February 20, 1998

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030-01609
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Dr. Gerald Bepko, Chancellor
Indiana University Medical Center
Administrative Building 104B
355 Lansing St.
Indianapolis, IN 46202

SUBJECT: NOTICE OF DENIAL OF AMENDMENT REQUEST

Dear Dr. Bepko:

This refers to letter dated August 27, 1996, submitted by Mack Richard of your staff which requested an exemption to certain requirements found in 10 CFR 71.5, "Packaging and Transportation of Radioactive Material." Based on our review of the information provided and as discussed with Mr. Richard, your request is denied. The basis for the denial is that you did not demonstrate a compelling reason for an indefinite exemption from certain regulations in 10 CFR 71.5. This was based on the following conclusions:

1. You state in your letter that Indiana University Medical Center is exempt from U.S. Department of Transportation's (DOT) Hazardous Materials Regulations (HMR) in 49 CFR. NRC review of DOT-HMR concludes that Indiana University is not specifically exempt from 49 CFR as implied in your letter. Your transportation activities generally lie outside the scope of DOT's jurisdiction. DOT statutes are limited to materials "in commerce." Shipments of government owned material by government employees in government vehicles that are not "in furtherance of a commercial enterprise" or "in commerce" are not subject to HMR. Since State university shipments usually meet these conditions, they are not subject to HMR. Therefore, State universities are not subject to DOT-HMR because this transportation does not meet the definition of "in commerce," not because DOT has made a determination that safety regulation of State university transportation is not needed. The fact that you are excluded from DOT regulation because your shipments are not in interstate commerce is not a compelling reason for granting exemption from NRC transportation safety regulations.

NRC became involved in regulating transportation activities due to a growing number of incidents attributed to the use of defective shipping containers or improper loading and preparation of packages for the shipment. The Commission issued an effective rule on November 11, 1979, for the sole purpose of assuring, through 10 CFR Part 71.5(a), that all shipments of NRC licensed material, including shipment of low specific activity and Type A quantities of radioactive materials (typical university shipments), are made in accordance with DOT regulations. A further limitation of DOT regulations, however, was that they applied (at the time) only to shipments in interstate commerce. Since many NRC licensees do not engage in interstate commerce, 71.5(b) was added to apply DOT regulations to all NRC licensed material transportation. Granting exemptions in this area would appear to be contrary to the intent of NRC's previous rulemaking.



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2. You state in your letter that it appears that most of your radioactive waste shipments are subject to 10 CFR 71.5 which references a significant number of 49 CFR regulations which are quite detailed and very cumbersome. DOT's HMR provides considerable flexibility to licensees because they are generally performance-based and not prescriptive. For example, packages must pass certain test criteria in order to be used for DOT. DOT does not specify how the package must be built. NRC has no technical basis to challenge the content of DOT's performance-based HMR. Given the level of flexibility HMR provides to licensees, and the general compliance on the part of several thousand licensees with HMR, NRC is unable to identify any unique burden HMR compliance poses to Indiana University Medical Center.
3. You provide alternate procedures in lieu of those required by 10 CFR 71.5. NRC believes a request for approval of alternate procedures under 10 CFR 71.5(b) should:
 - a. Stipulate that no radioactive material shipments are "in furtherance of a commercial enterprise."
 - b. Identify the problem posed by HMR compliance.
 - c. Provide the rationale for departure from the HMR.
 - d. Demonstrate that alternate procedures achieve equivalent safety.
 - e. Quantify the burden of compliance for the HMR and the alternate procedures.

The procedures suggested in your letter did not address and/or demonstrate the above criteria. Given the HMR's flexibility, it is difficult to propose a set of alternate procedures that significantly reduce the compliance burden that do not reduce the stringency of the requirements. If the procedures are less stringent than the HMR, equivalency with the HMR would need to be demonstrated.

4. You omitted important DOT regulations from your alternate procedures. For example, 49 CFR 173.475 contains numerous provisions on quality control requirements applicable before each shipment of radioactive material. Since your alternate procedures do not address quality control, they are not equivalent to DOT. Your alternate procedures need to consider the entire set of DOT regulations generally applicable to radioactive material transportation activities.
5. With regard to the specific alternate procedures proposed, NRC is unable to conclude that the proposed procedures for packaging and shipping papers are equivalent to those of DOT. The alternate packaging section states that all packaging "will withstand the normal rigors of transport." However, the proposed alternative provides no standards for packaging to assure that level of performance will be achieved. Since you are requesting exemption from federal safety standards for packages containing radioactive material, the absence of packaging standards is not acceptable.
6. The alternate procedures for shipping papers provided a description of the overall shipment, rather than per package as required by the HMR. This would provide information that is similar in nature to that required by DOT, but less in content and detail. In the event of an accident, it is not clear that emergency responders could identify packages containing certain radioactive material based on the information contained in your proposed shipping paper.

We conclude, based on the information you provided, that adequate justification for exemption to 10 CFR 71.5 was not provided and the alternate procedures provided do not appear to be equivalent to that of DOT. Therefore, your request for exemption is denied.

As provided in Section 2.103 of 10 CFR Part 2, enclosed, you have the right to request a hearing concerning this denial. If you wish to request a hearing, it must be submitted within 20 days from the date of this letter to the Secretary of the Commission, ATTN: Chief, Docketing and Service Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Assistant General Counsel for Hearings and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. The request should reference this letter and Docket Number 030-02764, as appropriate.

If you have any questions or require clarification on any of the information stated above, you may contact John R. Madera of my staff at (630) 829-9834.

Sincerely,

Original signed by
James L. Caldwell for

A. Bill Beach
Regional Administrator

License No. 13-02752-03
Docket No. 030-02764

Enclosures: 1. Ltr dtd 08/27/96 M. L. Richard,
Indiana University, to US NRC w/encl
2. 10 CFR 2.103

cc w/encls: Mack L. Richard, M.S.
Radiation Safety Officer

C. Michael Hart, M.D., Chairman
Radiation Safety Committee

***See Previous Concurrences**

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Docket No. 030-02764

Enclosure: 1. Ltr dtd 08/27/96
2. 10 CFR 2.103

cc: Mack L. Richard, M.S.
Radiation Safety Officer
C. Michael Hart, M.D., Chairman
Radiation Safety Committee

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