



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-8064

DEC 16 1993

Docket: 030-33056  
License: 11-27459-01

Bingham Memorial Hospital  
ATTN: Robert Peterson, Administrator  
98 Poplar Street  
Blackfoot, Idaho 83221

SUBJECT: NRC INSPECTION REPORT 030-33056/93-01 (NOTICE OF VIOLATION)

This refers to the routine, unannounced inspection conducted by Mr. Robert A. Brown of this office on November 3-4, 1993. The inspection included a review of activities authorized by Byproduct Materials License 11-27459-01. At the conclusion of the inspection, the findings were discussed with members of your staff. The inspection findings were also discussed during a telephone conversation between Ms. Linda Kasner of this office and Mr. Robert Peterson of your staff on November 5, 1993.

The inspection was an examination of activities conducted under the license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, independent measurements, and observation of activities in progress.

During this initial inspection, the inspector discussed with your staff the requirements with which you must comply, including the NRC and Department of Transportation regulations, and the commitments in your license application. The NRC enforcement policy was also discussed at this time.

Based on the results of this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice). The violations are of concern because they indicate a lack of attention to NRC requirements.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

It was determined by the inspector that nuclear medicine procedures and related activities at Bingham Memorial Hospital had been performed by a contractor working under the supervision of an authorized user. Although NRC

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regulations do not preclude such contractual arrangements, it must be emphasized that the licensee is responsible for maintaining compliance with NRC regulations. NRC regulations require that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements. This includes the responsibility for overseeing the activities of contractors working with licensed material at your facility.

An inspection finding of particular concern was the fact that you had procured radiopharmaceuticals from Teton Nuclear Medicine Service, an organization which was not licensed to distribute them. This issue is described as Violation A in the enclosed Notice. As was discussed with you during the exit briefing and during subsequent discussions with NRC Region IV staff members, 10 CFR Part 35 includes provisions which restrict the human use of radiopharmaceuticals to materials which are approved by the Food and Drug Administration (FDA) and obtained from authorized manufacturers, distributors, or nuclear pharmacies. However, the inspector confirmed that radiopharmaceuticals used at your facility were approved for human use by the FDA and were reconstituted and administered in accordance with the manufacturers' and authorized users' instructions.

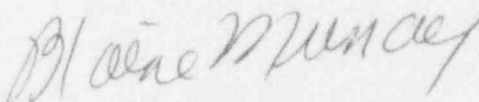
Normally, the human use of unauthorized byproduct material is considered a significant regulatory concern; however, based on the mitigating factors described above, this issue is being characterized as a Severity Level IV violation. Nevertheless, future violations of this nature may be considered for escalated enforcement action.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96.511.

Should you have any questions concerning this letter, please contact the inspector identified above at (817) 860-8100.

Sincerely,



*DC*  
Dwight D. Chamberlain, Acting Director  
Division of Radiation Safety  
and Safeguards

Enclosure:  
Appendix - Notice of Violation

Bingham Memorial Hospital

-3-

cc:  
Idaho Radiation Control Program Director

bcc:  
 DMB - Original (IE-07)  
 JLMilhoan  
 DDChamberlain  
 CLCain  
 RAScarano, RV  
 MMessier, OC/LFDCB (4503)  
 \*WLFisher  
 \*LLKasner  
 \*RABrown  
 \*NMIS  
 \*MIS System  
 \*RIV Files (2)  
 SLMerchant, NMSS/IMAB (6 H3)  
 \*W/IFS Form

*RIV:NMIS	AC:NMIS <i>JK</i>	AD:DRSS <i>JK</i>		
RABrown	LLKasner <i>JK</i>	DDChamberlain		
11/ /93	12/15/93	12/15/93		

\*Previously concurred

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