



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

JUN 4 1993

Docket: 030-10133
License: 49-15978-01
EA 93-163

Ivinson Memorial Hospital
ATTN: Thomas A. Nord, CEO
255 North 30th Street
Laramie, Wyoming 82070

SUBJECT: NRC INSPECTION REPORT 030-10133/93-01 (NOTICE OF VIOLATION)

This refers to the routine, unannounced inspection conducted by Mr. Gilbert L. Guerra, Jr., of this office on May 18, 1993. The inspection included a review of activities authorized by Byproduct Materials License 49-15978-01. At the conclusion of the inspection, the findings were discussed with members of your staff. The enclosed NRC Inspection Report 030-10133/93-01 documents this inspection.

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.

Based on the results of this inspection, three apparent violations were identified that are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C. These apparent violations relate to the failure to implement a quality management (QM) program in accordance with 10 CFR 35.32. Accordingly, no Notice of Violation is presently being issued for these inspection findings. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

The inspector noted that you had submitted a written QM program to NRC on January 21, 1992, but as of the date of this inspection had not effectively implemented that program. You are required to implement a QM program even though you are not licensed for radiation therapy or radiopharmaceutical therapy, because greater than 30 microcuries of sodium iodide I-131 are administered for diagnostic whole body scans.

The inspector found that you had administered greater than 30 microcuries of sodium iodide I-131 on three occasions in 1992 and 1993 for diagnostic whole body scans without preparing a written directive for each administration.

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These were the only administrations of sodium iodide I-131 that you had administered since the implementation of the QM program. It was found that you had administered 8 millicuries of I-131 on February 28, 1992, and 10 millicuries of I-131 on August 11, 1992, and April 5, 1993. Each of these administrations was ordered by an authorized user, and the patient's identity was verified by more than one method. Records of each administration of I-131 were kept but did not include a written directive.

The inspector found that inadequate supervision contributed to the licensee's failure to fully implement the QM program in that a trained individual failed to recognize the need for a written directive and administered doses greater than 30 microcuries without a written directive. Also, as of the date of this inspection you had not reviewed the QM program as required by 10 CFR 35.32(b) at intervals no greater than 12 months to include a representative sample of patient administrations and all recordable events since the programs implementation on January 27, 1992.

A telephonic enforcement conference to discuss these apparent violations has been scheduled for June 15, 1993, at 1:00 pm MDT. The decision to hold an enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. The purposes of this conference are to discuss the apparent violations, their cause and safety significance; to provide you the opportunity to point out any errors in our inspection report; and to provide an opportunity for you to present your proposed corrective action. In particular, we expect you to address the lack of implementation of the QM program as discussed in the report. In addition, this is an opportunity for you to provide any information concerning your perspectives on 1) the severity of the violations, 2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and 3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding the apparent violations is required at this time.

Also during this inspection, certain other of your activities appeared to be in violation of NRC requirements as specified in the enclosed Notice of Violation (Notice), Appendix A. The inspector found that you had obtained the services of a visiting authorized user for the period of March 6-13, 1993, but failed to obtain a copy of the user's NRC or Agreement State license in order to verify the qualifications of this individual.

You are required to respond to this letter in regard to this violation 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

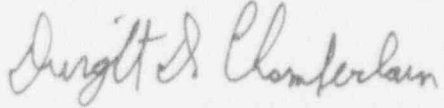
further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures 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 C. L. Cain of my staff at (817) 860-8186.

Sincerely,


for L. J. Callan, Director
Division of Radiation Safety
and Safeguards

Enclosure:

Appendix A - Notice of Violation
Appendix B - NRC Inspection Report
030-10133/93-01
Appendix C - Proposed Enforcement
Conference Agenda

cc:
Wyoming Radiation Control Program Director

bcc:

DMB - Original (IE-07)

JLMilhoan

LJCallan

DDChamberlain

MRodriguez, OC/LFDCB (4503)

*WLFisher

*CLCain

*GLGuerra

*NMIS

*MIS System

*RIV Files (2)

*REHall, URFO

GFSanborn, EO

WLBrown, RC

SLMerchant, NMSS/IMAB (6 H-3)

JLieberman, OE (7 H-5)

W/IFS form

RIV:NMIS <i>see</i>	C:NMIS <i>see</i>	D:DRSS <i>see</i>		
<i>see</i> GLGuerra	CLCain	LJCallan		
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RIV:NMIS <i>we</i>	C:NMIS <i>we</i>	D:DRSS <i>we</i>		
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