DMB

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV

Walnut Creek Field Office
1450 Maria Lane
Walnut Creek, California 94596-5368

February 6, 1997

Mr. Pat Linton, Executive Team Leader (CEO)
North Hawaii Community Hospital
67-1125 Mamalahoa Highway
Kamuela, Hawaii 96743

SUBJECT: RESPONSE TO NOTICE OF VIOLATION (NRC INSPECTION REPORT 30-34081/96-01)

Dear Mr.Linton:

Thank you for your letter of January 15, 1997, in response to our letter and Notice of Violation dated December 20, 1996. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. We will review the implementation of your corrective actions during a future inspection to determine that full compliance has been achieved and will be maintained.

Sincerely,

Frank A. Wenslawski

Frank A. Wenslawski, Chief
Materials Branch
Division of Nuclear Materials
Safety

Docket No.: 30-34081
License No.: 53-29099-01

IE-01

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NORTH HAWAII COMMUNITY HOSPITAL

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January 15, 1997

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

SUBJECT: **Reply to a Notice of Violation**
NRC inspection 30-34081/96-01

Dear NRC:

We are in receipt of your letter and Notice of Violation dated December 20, 1996. The following responses are in references to the items listed on the "Notice of Violation".

A. 1. Quality Management Program. As stated in the Notice of Violation, all of our users have not read the Quality Management Program for this license. Although ours is a new license, the large majority of our users were formerly authorized users at a site directly adjacent to us. This nearby site closed in conjunction with the opening of our facility. The users assumed that the conditions of our license were identical to their previous license and they were not made aware of a few changes which were instituted with our license. To remedy this, all of our authorized users and technologists have been asked to review and acknowledge in writing their understanding of our program and procedures. This should be completed within the next thirty days and this record will be kept on file in the Nuclear Medicine department log. Any new users added to our license will be required to do the same.

2. Procedures for Administering 1-131 Doses. As pointed out in the Notice of Violation one of our users did administer 2 doses of 1-131 which were in excess of 10 mCi and the required bioassays were not performed on himself and the nuclear medicine technologist who was present. This user has worked at other NRC licensed sites where a bioassay was only required for 1-131 doses in excess of 30 mCi and at the time of the administrations at our site he was not aware of the different requirement in our license. In the next 30 days we will be contacting the NRC to modify our license so that the dose level requiring a bioassay is changed from 10 to 30 mCi. Until a formal change is granted we will be performing bioassays in accordance with our license.

B. Dose calibrator test for geometry dependence. The nonperformance of this required test during installation was an oversight on the part of our Physicist. The Dose calibrator in question actually came from a separately licensed site directly adjacent to ours and the requirement to recheck the geometry dependence after this short move was overlooked. When this deficiency was was discovered the inspector immediately instructed us to perform this test before this calibrator was used for preparing any further patient doses. We have performed this test and have documented results that are within acceptable limits.

C. Incomplete written directive. As stated in the Notice of Violation, one of our users did not completely fill in the patient's name on the written directive for a 1.96 mCi dose of 1-131. This was an oversight on the part of the user and the technologist. It occurred because both the user and the

technologist were both very familiar with the case and a verbal communication of the name, agent and dose accompanied the incomplete written directive. This deficiency was not detected because there were many other written documents with the patient's name in the patient's folder and it was assumed that this was the dose for this patient. Fortunately because of the very low volume of patients in our nuclear medicine department we were able to confirm that this dose was actually given to the correct patient. The individual user and technologist involved in this oversight were present at the time of the inspection and the importance of this requirement were reviewed. The nuclear medicine technologist was instructed never to place an order without a clear and complete written directive from an authorized user.

In addition to the above specific violations, the letter of December 20, 1996 also noted other deficiencies in the implementation of our quality management program. As discussed in the above responses, many of our shortcomings are related to the fact that the large majority of our authorized users practiced at a closely adjacent facility which closed down when we opened our new facility; these users were under the incorrect assumption that our new license was identical to their old license. Unbeknownst to these users, the physicist who we contracted to prepare our new license application inserted several items which were significantly different from the routine at the former site. The users were not consulted during the application process and they were not aware that the new license contained these different requirements. To rectify the situation, we have undertaken a review of our current policies and procedures with special attention to the differences between our license and the users' former license. As stated above, all of our authorized users will be reviewing our current Quality Management Program and will be required to acknowledge, in writing, their understanding of our program within the next thirty (30) days.

If there are any other questions, concerns or comments please contact our Radiation Safety Officer, George Ainge, MD, at (808) 881-4880.

Sincerely,

Pat Linton

Pat Linton, Executive Team Leader

cc: Regional Administrator
Nuclear Regulatory Commission, Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

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