UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

JUL 02 1993

Docket No. 030-11883
License No. 53-16929-01
EA 93-040

Castle Medical Center
ATTN: John Monge
Vice President
Business Outpatient Services
640 Ulukahiki Street
Kailua, Hawaii 96734-4498

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTIES - $7,500

This refers to your two letters dated April 30, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalties (Notice) sent to you by our letter dated March 31, 1993. Our letter and Notice described nine violations identified by the NRC during an unannounced inspection conducted on February 9-11, 19, and 22, 1993.

To emphasize the need for effective management oversight of your Quality Management Program (QMP) and Radiation Safety Program, civil penalties of $7,500 were proposed.

In your response you denied Violations A.1, A..2, A.3, and F, and a portion of Violation D. You also argued that Violation E should not have been cited. You admitted Violations B, C, G, H, and I as documented in the Notice. Additionally, you requested remission of the civil penalties.

Based on your response, we have withdrawn the portion of Violation D relating to the failure to source check the Victoreen pancake probe. Violation D remains a violation, however, because there was a failure to source check the Xetex survey meter, as admitted in your response. After consideration of the remaining responses, we have concluded for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalties, that withdrawal of the violations or remission of the civil penalties is not warranted. Accordingly, we hereby serve the enclosed Order on Castle Medical Center imposing civil monetary penalties in the amount of $7,500.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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Your responses to two of the violations appear to contain inaccurate information. In response to Violation A.1, you indicated that written directives have contained all necessary information since December 16, 1992 whereas, according to the Chief Technologist, on December 21, 1992, a nine millicurie phosphorous 32 dosage was administered before the written directive was dated and signed by the authorized user. In response to Violation A.2, you stated that the annual review of the quality management (QM) program indicated only one administration where no written directive was found, and that the written directive for that administration was later found. However, the consultant's report of the annual review of the QM program dated January 7, 1993, indicates that there were two written directives missing, not one. Providing inaccurate information may be a further symptom of the lack of sufficient management attention to assure compliance with NRC requirements. In addition, providing inaccurate information to NRC is, in and of itself, a violation of 10 CFR 30.9 and may be the subject of further escalated enforcement action. Therefore, in order to determine whether inaccurate information was provided and whether further enforcement action is warranted, please provide to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, within 30 days of the date of this letter, the following information, in writing and under oath or affirmation:

A. A response, based on a thorough review of your April 30, 1993, letters, identifying any information in those letters that is either incomplete or inaccurate.

B. In regard to all inaccurate information that was provided: (1) indicate how the inaccuracy occurred; (2) describe actions taken or planned to assure that, in the future, information and records provided to, or maintained for, the NRC are complete and accurate in all material respects; and (3) state why the NRC should have confidence that, in the future, you will comply with the requirement in 10 CFR 30.9 to provide NRC with information that is complete and accurate in all material respects.

In your response to Violation B, you stated that if the dose calibrator is not operational, you will use individual dosages ordered from the radiopharmacy. Such action would violate 10 CFR 35.53(a) and (b), which require in part that the Licensee measure the activity of each radiopharmaceutical dosage before medical use.

In your response to Violation G, you state that a self-paced training program has been established for all nuclear medicine technologists and that the review of all procedures by the technologists will be documented annually. However, your

response did not indicate how the results of a self-paced training program will be verified by management.

In your response to Violation I, you state that Castle Medical Center has a policy of not performing in-patient therapy procedures and that therapy doses will not be administered to in-patients until they are discharged. However, your response did not indicate how you plan to prevent the failure to implement your procedures for in-patient therapy given a situation similar to that in Violation I.

Information regarding the deficiencies identified in your responses, as noted above, should be mailed to the Director, Office of Enforcement, at the above address, with a copy to the Regional Administrator, Region V, 1450 Maria Lane, Walnut Creek, California 94596-5368.

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

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosures: As Stated