UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
Calhoun General Hospital	)	Docket No. 030-18989
Grantsville, West Virginia	)	License No. 47-19621-01
	)	EA 93-096

DEMAND FOR INFORMATION

I

Calhoun General Hospital (Licensee) holds Byproduct Material License No. 47-19621-01 (License), issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. The License authorizes the Licensee to administer greater than 30 microcuries of sodium iodide I-125 or I-131, under 10 CFR 35.200. The License, originally issued on January 8, 1981, was renewed on April 1, 1991, and is due to expire on April 30, 1996.

II

The NRC's "Quality Management Program and Misadministrations" rule became effective January 27, 1992. This rule amended the regulations in 10 CFR Part 35 for Medical Use Programs for therapeutic administrations of radiation from byproduct material, certain uses of radioactive sodium iodide, and therapeutic administration of radiopharmaceuticals. Under the new requirements, established in Sections 35.25 and 35.32, licensees must implement and maintain a written Quality Management (QM) program to provide high confidence that byproduct material or radiation from byproduct material is administered as directed by an authorized user, and must train supervised individuals in the QM program and require the supervised individuals to follow the Licensee's QM procedures. In accordance with 10 CFR 35.32, licensees who use byproduct

material for teletherapy, gamma stereotactic surgery, brachytherapy, radiopharmaceutical therapy, and/or sodium iodide I-125 or I-131 in dosages greater than 30 microcuries, were required to submit to the licensee's NRC regional office, on or before January 27, 1992, a copy of the licensee's written QM program and a written certification that the program had been implemented. By letter dated April 8, 1992, NRC explained that if a licensee was authorized under its NRC license to use byproduct material that requires a QM program, but was not currently planning to use such materials, the NRC has given the licensee the option, in lieu of submitting a QM program, to submit to the Licensee's NRC regional office a written statement certifying that these materials were not being used. Under this option, if the licensee plans to use such materials later, the licensee was required to submit a written QM program prior to that use. Between July 25, 1991 and September 10, 1992, the NRC sent to all medical licensees information concerning this new rule and its implementation.

The License issued to the Licensee authorizes the use of byproduct material under conditions that require the Licensee to implement and maintain a written QM program. To date, the Licensee has neither submitted a copy of its QM program to the NRC Region II Office and a written certification that the program had been implemented, nor submitted a written statement to certify that byproduct materials that require a QM program are not being used.

This demonstrates that the Licensee has violated NRC requirements and raises a question as to whether the Licensee has a QM program currently in compliance with 10 CFR 35.25 and 35.32. Therefore, further information is needed to

determine whether the Commission can have reasonable assurance that the Licensee has complied with 10 CFR 35.25 and 35.32 and will continue to do so in the future.

III

Accordingly, pursuant to sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR 30.32(b), in order for the Commission to determine whether your License should be modified, suspended or revoked, or other enforcement action taken to ensure compliance with NRC regulatory requirements, the Licensee is required to submit to the Regional Administrator, Region II, 101 Marietta Street, N.W., Atlanta, GA 30023 within 30 days of the date of this Demand for Information, the following information, in writing and under oath or affirmation:

1. State whether or not you have implemented and maintained a written QM program that complies with the provisions of 10 CFR 35.32 and have implemented effective supervision of the program in accordance with 10 CFR 35.25. If so, indicate the date that the QM program was fully implemented.

2. State whether or not you submitted a copy of your QM program to the NRC Region II Office. If so, provide the date of the submission, and provide a copy of the QM program with your response to this Demand. If you are responding to this question by providing the date you submitted your QM program and a copy of the QM program, then you need not respond to questions 3 through 5.

3. State whether or not you submitted to the NRC Region II Office a written statement certifying that byproduct materials that require a QM program were not being used. If so, provide the date of the submission and provide a copy of the statement with your response to this Demand. If you are responding to this question with the date you submitted this statement and a copy of the statement, then you need not respond to questions 4 through 5.

4. Indicate whether you possessed or used, on or after January 27, 1992, byproduct material that requires a QM program. If so, state the byproduct material(s) possessed or used, the procedure(s) performed, and the dates of the possession or use.

5. If you have responded to question 4 stating dates of use of radioactive materials requiring a QM program, then you must submit an explanation as to why you did not comply with 10 CFR 35.32, and why NRC should not take enforcement action for violation of 10 CFR 35.32.

Copies of your response to this Demand also shall be sent to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, D.C. 20555 and Assistant General Counsel for Hearings and Enforcement at the same address.

After reviewing your response, the NRC will determine whether further action is necessary to ensure compliance with regulatory requirements.

FOR THE NUCLEAR REGULATORY COMMISSION

Stewart D. Ebneter
Regional Administrator

Dated at Atlanta, Georgia
this 5th day May 1993