

April 8, 1997

Mr. Robert W. Goff, Director  
Division of Radiological Health  
State Department of Health  
3150 Lawson St.  
P.O. Box 1700  
Jackson, MS 39215-1700

SUBJECT: REQUEST FOR INFORMATION

Dear Mr. Goff:

During a recent telephone discussion, you requested the details concerning a specific casework file that was reviewed during our review of your Radiation Control Program on January 27-31, 1997. The specific file was that of Cardiovascular Associates, P.A., Jackson, MS.

During our review, the review team did not develop any recommendations as the result of this specific casework; therefore, in accordance with our policy only a brief documentation was included in Appendix D of the Draft Report that was sent to you dated March 20, 1997. At your request, I reviewed and documented additional details on this case file, and these details are enclosed.

We have also received other inquiries concerning the review of this case, and the information provided in the enclosure as **Additional Details** and **Independent Case Evaluation** were provided as requested.

If you have any questions, please feel free to call me at any time.

Sincerely,

*RS*  
Richard L. Woodruff  
Agreement State Program Officer

Enclosure: Details

OFFICE	DNMS BASO	DNMS DO				
SIGNATURE	<i>RLW</i>	<i>Chasey</i>				
NAME	RWoodruff	Chasey				
DATE	04 / 8 / 97	04 / 8 / 97	04 / / 97	04 / / 97	04 / / 97	04 / / 97
COPY?	YES X NO	YES <u>NO</u>	YES NO	YES NO	YES NO	YES NO

OFFICIAL RECORD COPY DOCUMENT NAME: P:\MS\GOFF.RLW

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## DETAILS ON CARDIOVASCULAR ASSOCIATES CASEWORK

The following license casework was reviewed during the IMPEP review and the information documented in the draft report as follows:

File No. 16

Licensee: Cardiovascular Associates, P.A.

Location: Jackson

License Type: Medical

Date of Amendment Issued: 01-16-96

License No.: 804-01

Amendment No.: 1

Type of Action: Renewal

License Reviewer: BJS

### Comment:

- a 3/22/96, request to add physician as Authorized user. 4/3/96 deficiency letter, requesting clarification of training dates. 9/6/96 letter from Baptist Medical Center attesting to physicians competency over last 13 years. Specific dates for the 500 hours of supervised work experience and 500 hours of supervised clinical experience requirements were not provided. The license was issued.

No recommendations were made by the team concerning the above casework; therefore, additional details were determined not to be needed in the IMPEP report.

### Additional Details:

During the selection of the casework, Mr. Goff requested that the team specifically evaluate State actions concerning this case. In response, Mr. Woodruff requested the following four issues be addressed by the case reviewer: (1) the technical training qualifications required for licensure of Cardiologists under the Regulations for Control of Radiation in Mississippi, (2) the technical procedures utilized by the Division of Radiological Health (DRH) to evaluate license applications for health and safety, (3) the documentation and evaluation of preceptor type records in the license files, and (4) the adequacy of the license issued to Dr. Thompson as a user of radioactive materials on the license issued to Cardiovascular Associates, P.A..

The team verified that: (1) the technical training qualifications of the Mississippi regulations, Section 801.G.67, are equivalent to the NRC regulations, 10 CFR 35.920; (2) equivalent technical procedures were utilized (based upon file documentation and staff interviews) by the DRH in the review of the MS-804-01 license application and amendment applications; (3) preceptor records are maintained in the license file; and (4) the license issued was technically adequate to address health and safety issues. Under NRC jurisdiction, the experience and training received under the supervision of a private practitioner would have been accepted.

### Independent case evaluation:

The following information was obtained from the case file by Mr. Woodruff and documented as follows:

1. The initial request to add Dr. Thompson to the license came from Dr. Hester, Jr. on February 26, 1996, and indicated that clinical experience

had been received under him at the Cardiovascular Associates, P.A. facility. [This did not meet the Mississippi requirements for licensing specified in Section 801.G.67(b) of their regulations because of the institutional requirement in the MS regulations. This requirement is more restrictive than the NRC requirement.]

2. DRH requested additional information detailing the experience and training received by Dr. Thompson.
3. This additional information was received from Dr. Hester on March 22, 1996 and indicated that the necessary experience was received at both the Mississippi Baptist Medical Center (an institutional license) and at Cardiovascular Associates, P.A. (a private clinic).
4. On April 3, 1996, the DRH informed Dr. Hester that the supervised work experience and the supervised clinical experience must be performed under an authorized user at a "medical institution."
5. On September 6, 1996, the Director, Department of Environmental Health, Mississippi State Department of Health received a letter from the Medical Director, Mississippi Baptist Medical Center (MBMC), attesting that Dr. Thomas A. Thompson had easily met or exceeded the 500 hours of supervised work experience and the 500 hours of supervised clinical experience while being affiliated with the institution for over 13 years.
6. On September 9, 1996, Dr. Thomas A. Thompson provided a copy of the Medical Director's letter dated 9-6-96 to the DRH, and requested that the previous application be reactivated and this additional information from the Medical Director, MBMC, be considered.
7. The Department of Environmental Health and the DRH reviewed this additional information from the Medical Center concerning the preceptor experience and training. Based upon this experience, the DRH amended the license on September 12, 1996 with Dr. Thompson listed as an authorized user.

#### Additional Comments and Follow-up Actions

The documents on file appeared to be complete, authentic and properly signed.

The casework was discussed with Mr. Goff during the review, and the team committed to providing additional information concerning our policy on the review of training and experience of medical applicants, and the NRC definition of medical institution.

The process by which the State evaluates an application is an internal process under the jurisdiction of the State. It was noted that the DRH requires the preceptor to be an authorized user, and in cases where the experience and training of applicants can't be readily determined by the license reviewers, that guidance can either be obtained from the Mississippi Radiation Advisory Council, or up through the organization of the State Health Officer. This

process does not conflict with NRC policy. Issues regarding the approval of cases that can't be readily determined by the technical staff should be addressed by the State Health Office. The State followed their process in this instance and the process does not conflict with NRC procedures referenced in PG 3-16, Review of Training and Experience Documentation Submitted by Proposed Physician User Applicants.

On March 11, 1997, a copy of the NRC Policy and Guidance Directive PG 3-16, dated 12/12/95 was faxed to B.J. Smith.

Note (no date) from Sally Merchant that a package had been sent to the State with a copy of PG 3-16; excerpts from a Technical Assist Request (TAR) containing clarification of the term "medical institution;" PG-3-15, Standard Review Plan for the Review of Licensees' Submitted Quality Management Programs; and the Information Notice 94-17, Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use.