



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005**

February 14, 2006

Wilcox Memorial Hospital
ATTN: Lee A. Evslin, M.D.
President & CEO
3420 Kuhio Highway
Lihue, Hawaii 96766

**SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST INVOLVING AN
EXEMPTION FROM 10 CFR 35.433(a)**

Dear Dr. Evslin:

This letter responds to your letter dated November 20, 2002, in which you requested an exemption from the requirements in 10 CFR 35.433(a). This exemption, if granted, would authorize Mr. Ronald Frick and Mr. Philip Manley of Gamma Corporation to perform decay calculations of the Sr-90 sealed sources used for ophthalmic treatments in the Wilcox Memorial Hospital. In our letter dated February 9, 2005, we requested that you provide additional information in support of your exemption request. Your February 15, 2005, letter provided an outline of Mr. Frick's experience in performing decay calculations and reviewing ophthalmic treatment data. The information provided in your letter was specific to Mr. Frick's abilities to determine the proper exposure times, source activities, and his ability to ensure that the proposed dose calculations correspond to the delivered doses prescribed in the written directives. Additionally, in your documentation, you provided the total number of hours of training and experience that Mr. Frick had completed that were specific to therapeutic modalities and the use of Sr-90 ophthalmic sources. You also stated in your letter that Wilcox Memorial Hospital had withdrawn its request to authorize Mr. Manley to perform decay calculations of Sr-90 ophthalmic sources.

In response to your exemption request, Mr. Frick's credentials outlining his training and experience were presented to the Advisory Committee on Medical Uses of Isotopes (ACMUI) on October 25, 2005. After reviewing Mr. Frick's credentials, the ACMUI, by majority vote, voted against approving the requested exemption from 10 CFR 35.433(a). In the ACMUI vote, four members voted against recognizing Mr. Frick as an Authorized Medical Physicist (AMP) restricted only to Sr-90 eye application, three members voted in favor and two members abstained. Both a medical physicist and a radiation oncologist were among the ACMUI participants that voted against approving Mr. Frick's credentials. The second radiation oncologist was absent during voting.

In its deliberations on Mr. Frick's credentials, the ACMUI concluded that he did not have sufficient experience in using a Sr-90 applicator, nor was he qualified to review the treatment data. Additionally, some members of the ACMUI expressed their concerns that the chances of any medical event would be much lower if an AMP or brachytherapy physicist performed the medical physics aspect associated with the Sr-90 ophthalmic procedure.

Wilcox Memorial Hospital in its August 19, 2003, letter indicated that prior to 2002 less than two Sr-90 eye application procedures were performed per year. Wilcox Memorial Hospital also indicated that it had not performed any ophthalmic treatment procedures since 2002. The reason given by you for not performing ophthalmic treatments was due to not having an AMP. In its review, the ACMUI expressed its concern that this low treatment frequency did not provide the licensee's Authorized User (AU) with adequate clinical experience and therefore, in the absence of an AMP, there would be an increased risk for a medical event.

Research by the NRC has shown that the majority of eye applicator medical events are attributed to errors in the decay calculations. However, the ACMUI stated that there are other causes of medical events that a qualified AMP could assist the AU in preventing. One example provided by the ACMUI included the failure to remove the cap on the source before using the source on the eye of the patient.

One member of the ACMUI noted that many AMPs are available in the State of Hawaii, and that Wilcox Memorial Hospital may have only considered the unavailability of an AMP on the island of Kauai.

The NMSS staff agrees with the ACMUI recommendation and based on the ACMUI recommendations is not able to grant Wilcox Memorial Hospital an exemption from the requirements of 10 CFR 35.433(a). In particular, NMSS staff finds that Mr. Frick's training and experience does not qualify him to perform the decay calculations or other medical physics aspect of the ophthalmic treatment procedure to warrant granting the requested exemption. In this case, the committee members in specialties most closely aligned with medical physics and brachytherapy voted against granting Wilcox Memorial Hospital an exemption from 10 CFR 35.433(a). Furthermore, NMSS staff places great weight on the views of the ACMUI. The NRC staff relies heavily on the ACMUI, NRC's advisory body, in reviewing qualifications of medical professionals.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation. If you have any additional questions please contact Ms. Jackie Cook at 817-860-8132 or the undersigned at 817-860-8197.

Sincerely,

/RA/

Jack E. Whitten, Chief
Nuclear Materials Licensing Branch

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SUNSI Review Completed: Yes _____ ADAMS: X Yes No Initials: JDC1
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