

From: Sandra Gabriel
To: Mmannix@ghs.guthrie.org
Date: Thu, Sep 23, 2004 5:42 PM
Subject: NRC license amendment request, mail control 135608

Mary:

I am now officially assigned to work on your amendment request dated August 31, 2004. Please provide the following additional information:

1. Regarding your proposal to add Dr. Durakovic as authorized user, we can authorize him for 35.100, 35.200, 35.300, and in vitro studies, based on his 1983 certificate from the American Board of Nuclear Medicine. However, as required by 10 CFR 35.59, we need documentation of related continuing training and experience in the past 7 years. One way to provide this is to submit a copy of another license listing Dr. Durakovic as an authorized user for these uses. You also requested to authorize Dr. Durakovic for 35.400. American Board of Nuclear Medicine certification is not adequate to authorize him for brachytherapy uses under 35.400. Authorized users for 35.400 must document the information required by either 35.490 and 35.940. Nuclear Medicine physicians typically do not meet these requirements.

2. Regarding your proposal to add Dr. Welt as an authorized user for non-medical uses, please note that your current license does not allow non-medical use for three of his requested uses: Indium 111, Yttrium 90, and Iodine 131. If you wish to add these to your license, please provide detailed information about the types of studies to be performed; the amount of activity to be used per study, maximum amount on hand at any one time, and maximum possession limit (including waste); facilities; and equipment. Specialized facilities may be needed if you propose to use Iodine 131 in greater than microcurie quantities in a form that may become airborne. These isotopes are most frequently used in human or animal studies; please indicate whether you propose to perform in vivo animal studies. For all isotopes to be used by Dr. Welt, please document his hands-on experience using similar isotopes and quantities.

3. Regarding your proposal to add Dr. Durakovic as Radiation Safety Officer (RSO), please note that we do not have access to the referenced license from the VA Medical Center in Wilmington, Delaware. NRC has granted a Master Materials License to the VA system, and they now retain all of these records at their centralized facility. If Dr. Durakovic qualifies as an authorized user, this may be sufficient for us to authorize him as RSO. However, 10 CFR 35.50(2)(c) states this is permitted if he "has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities." Therefore, please document that Dr. Durakovic has experience with radiation safety aspects of 35.400 brachytherapy, high dose rate remote afterloading brachytherapy, and the research uses authorized by your license, or that he will receive this training prior to assuming his duties as RSO.

Please respond within 30 days. You may fax your response to 610-337-5269, referencing mail control 135608. If you would like to discuss these issues, please call me at 610-337-5182 or respond by e-mail.

Thank you,

Sandy Gabriel
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Division of Nuclear Materials Safety