From: Sandra Gabriel
To: Goldschmidt-Ed@cooperhealth.edu
Date: Thu, Aug 18, 2005 11:11 AM
Subject: Additional information needed for NRC license renewal, The Cooper Health System, mail control 136936

Reference:
The Cooper Health System
license 29-08285-01
docket 03002512
mail control 136936

To: Ed Goldschmidt, RSO

Please provide the following additional information within 30 days. You may fax your signed response to 610-337-5269, referencing mail control 136936. You may wish to leave a voicemail or e-mail message to alert me when you send the fax.

Please send an e-mail to confirm receipt of this message.

1) Page 9 of your application states that the materials in Item 5, letters F through J are in storage with the intent to transfer to an authorized recipient. Please describe the status of your efforts to dispose or transfer this material. What is the nature of the hydrogen-3 and carbon-14 in Items 5.I. and 5.J., and how long has it been in storage?

2) Item 5.F. of your application lists Am-241 source Amersham Model AMC.24. Is this one or more old x-ray fluorescence analyzer sources? (Sealed Source and Device Registry lists AMC.24 under registration 1L-0136-S-834-S with a maximum activity of 20 mCi each. You requested authorization for 28 mCi.)

3) Please note that the Amersham CDC.T1 sources in Item 5.G. will be listed as AEA Technology Model CDC.T1, to match the current Sealed Source and Device Registry listing.

4) Is the Sr-90 sealed source in Item 5.H. your old eye applicator? You provided the Amersham serial number, but not a model number. Are you able to identify the model number?

5) Item 6, bottom of page 9, of your application lists the information that you agree to submit to NRC for approval prior to in-vitro or animal use of radioactive material for research and development purposes. Please confirm that you will submit this information in accordance with the guidance presented in both Volumes 7 and 11 of the NUREG-1556 series.

6) Page 12 of your application presents your request for additional flexibility to make program changes under your broad license. Please confirm that you are requesting additional flexibility for medical uses only and that you will address flexibility for research and development uses in future amendment requests.

7) Item 7.2.C of your application addresses your criteria for new uses and users. You committed to evaluate authorized users for 35.1000 technologies using the then-current guidance on the NRC public website. Please confirm that you will use the same approach to evaluate authorized medical physicists (for the technologies that require an AMP to be named, such as intravascular brachytherapy).

8) Item 10.2 of your application addresses radiation monitoring instruments. Please provide a listing of types of instruments currently in use/available for use.

9) Item 10.4 of your application states that bioassays will be performed for liquid I-131 administrations involving greater than or equal to 1 mCi, but bioassays will be performed for capsule I-131 therapy treatments only if there is a problem during administration (capsule

breaks, patient vomits, etc.). Please provide the basis for this policy, for example, did your Radiation Safety Committee perform a historical review of data.

10) Item 11 of your application addresses Waste Management. As described in NRC Regulatory Information Summary 2004-17, there is no longer a requirement for a specific holding period for decay-in-storage. You may withdraw your commitment to hold waste for a minimum of 10 half-lives. This requirement has been removed from the standard license condition and will be updated on your license.

11) Your application included an HDR quality assurance policy and procedure and a daily HDR therapist QA protocol describing your program for compliance with 10 CFR 35.643. Please submit the details of the method used for spot-checks of timer accuracy, including the tolerance range of acceptable results.

12) Your submitted HDR quality assurance policy and procedure says that the spotcheck is performed daily by a technologist or physicist trained by an authorized medical physicist (AMP). Confirm that you will comply with the 35.643(a)(3) requirement for a spot-check to be performed after each source installation and the requirement of 35.643(c) for an AMP to review the results of each spotcheck within 30 days.

13) Please note that your request to remove depleted uranium from your license will be addressed separately from the license renewal.

14) Please note that we will initiate, under a new mail control number, a licensing action to terminate your irradiator license. The amendment terminating the irradiator license will be issued at the same time as the renewal of your broad license.

Thank you for your help. If you have any questions, you may e-mail me or call at 610-337-5182.

Sandy Gabriel
Senior Health Physicist
Medical Branch
NRC Region I

Mail Envelope Properties
(4304A52D.F10 : 8 : 27167)

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From: Sandra Gabriel

Created By: SLG2@nrc.gov

Recipients
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Options

Expiration Date:	None
Priority:	Standard
Reply Requested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard