**From:** Sandra Gabriel
**To:** Goldschmidt-Ed@cooperhealth.edu
**Date:** Sat, Aug 11, 2007 7:14 PM
**Subject:** Additional information for NRC license amendment request, mail control 140880

Licensee: The Cooper Health System, Robert Wood Johnson Medical School at Camden
License No.: 29-08285-01
Docket No.: 03002512
Control No.: 140880

To: Ed Goldschmidt, RSO

This is regarding your amendment request dated July 26, 2007 to authorize clinical use of your Perfexion gamma knife. Please provide the following additional information under management signature within 30 days. You may mail, FedEx, or fax your signed response to my attention Region I, referencing mail control 140398.

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

1) Future AU and AMP approvals: Your request stated that your Radiation Safety Committee will follow the NRC's Perfexion licensing guidance criteria for approval of Authorized Users and Authorized Medical Physicists under your broad license. Please note that AU and AMP criteria may be revised in the future, and may become more restrictive. Please confirm that after your initial AU and AMP approvals under the current licensing guidance, you will review and follow any changes in the guidance in effect at the time of future approvals.

2) RSO training: In addition to criteria for approval of AU's and AMP's, the NRC's Perfexion clinical use licensing guidance includes criteria for approval of RSO's. We approved you as RSO for the Perfexion possession/testing license, before development of the clinical use licensing guidance, based on your commitment to receive vendor training in emergency procedures prior to operation of the Perfexion unit by Cooper personnel. Please provide documentation that you have now received training in the radiation safety, regulatory issues, and emergency procedures for the Perfexion unit, provided either by the Perfexion vendor or by an AMP or AU who received training from the vendor. Describe the nature and duration of the training and the training provider. Also document that you have completed hands-on radiation safety and emergency procedures training on your newly-installed Perfexion unit.

3) Monthly spot-check of treatment table retraction mechanism: Please clarify how your proposed test will specifically demonstrate that the table retraction mechanism works under backup battery power with the unit turned off, as required by 35.645(c)(1)(i).

4) Monthly spot-check of emergency timing circuits: Your amendment request described the function of the timer monitoring circuits, but did not describe the test you plan to perform. We understand that it may not be feasible to create a test situation that causes a disparity in timers in order to demonstrate that the system alarm functions correctly. Please clarify how you intend to perform your spot-check, for example, during a test run, compare the primary and secondary elapsed timers, and confirm that the elapsed shot time plus elapsed time equals the planned shot time, with an allowable tolerance of 0.1 minutes. We also understand that the time parameters are also displayed on an LED panel accessible behind the treatment unit. You might consider comparing the elapsed time on the LED panel with the elapsed time at the control console to assure that you will have an accurate record of the delivered treatment if you lose power to the control computer.

5) Monthly spot-check of stereotactic frames: Your amendment request did not address the requirement of 35.645(c)(1)(iv) to perform a monthly spot-check of stereotactic frames. [The trunnion portion of this requirement is not applicable, however the stereotactic frame check is

still applicable and required.] For example, will you fit each frame into a test tool and confirm that it fits correctly?

6) Monthly spot-check of timer linearity: Please assure that your check includes measurements at a minimum of 3 timer settings, covering your full range of clinical timer use, and will be adjusted as treatment durations increase due to source decay or as new treatment techniques are adopted. The term "dose rate" was used in your written procedure, which we presume means an integrated measurement for one timer setting, divided by the set time, and corrected for on-off error, if applicable.

7) On-off error: Please clarify the meaning of the phrase "with isocenters" in your on-off error procedure. Also specify the collimator aperture size to be used for your test of on-off error. [Our understanding is that it is possible the design of the Perfexion's collimation system may result in different on-off errors for different aperture sizes, because the distance traveled by the sector drive unit from the "off" position to the 16 mm apertures is longer than the distance from the "off" position to the 8 mm or 4 mm apertures.]

8) Monthly spot-check of location of radiation focal point with respect to table position: It appears that your submitted "Focus precision check" will be used to fulfill this requirement. Steps 8 and 9 of your procedure present options of saving or discarding the results of the check. Please note that you are required to maintain a record of each required spot-check for 3 years.

9) Frame adapter check: At the bottom of page 8 of your request, you stated "proper operation of the frame adapter and docking device will be evaluated during the test runs for the daily spot checks," however you did not provide your criteria for determining proper operation. On the bottom of page 11, you listed a monthly frame adapter check, including a description of the specific criteria that you will use to evaluate the operation of the frame adapter and its attachment to the docking device. Are these the criteria you will use for your daily check?

10) Although not required by regulation or by the licensing guidance, you may wish to consider adding to your daily spot-checks confirmation that a calibrated survey meter is present in the control area, and confirmation that the shielding door ratchet tool and emergency procedures placards are present and free from damage.

11) Although not required by regulation, a number of the commitments from the licensing guidance called for the description of records of tests to be included in spot-check procedures (which are then required to be submitted to the NRC). Please submit a description of records of daily and monthly spot-checks, for example, a copy of the forms you plan to use.

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

Sandy Gabriel, Ph.D.
Senior Health Physicist
Medical Branch
NRC Region I

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