From: Sandra Gabriel
To: Sandy Snapp
Date: Wed, May 24, 2006 7:32 PM
Subject: Additional information for NRC amendment request, mail control 138887

Licensee: Riverside Regional Medical Center
License No.: 45-09001-01
Docket No.: 03003330
Control No.: 138887

To: Sandy Snapp, Gamma Knife Administrator
Harold Prussia, RSO

I have reviewed your May 23, 2006 request to authorize clinical use of your new gamma knife unit. In order to meet your schedule, the following items need to be resolved over the next couple of days. (Item 1 repeats issues that we have already discussed, informally, in e-mails over the last day.)

1) Please update your emergency procedures, RSO policy 36-03, to include two more items to fully meet the requirements of 10 CFR 35.610:

a) Address additional measures that you will take in emergency situations to restrict access to and post the treatment room door.

b) Include the names of individuals responsible to implement corrective actions, as well as the names and telephone numbers of the authorized users, authorized medical physicist, and Radiation Safety Officer to be contacted if the unit or console operates abnormally.

2) The submitted spot-check procedures appear to have 3 key components: the list of tests to be performed in RSO policy 36-04, the procedures in RSO policy 36-05, and and the spot-check forms. It is necessary for these 3 components to be internally consistent and also to cover all required elements in 10 CFR 35.645. The following issues need to be resolved to achieve internal consistency and to cover all regulatory requirements:

a) RSO policy 36-04, item 5) lists tests to be included in monthly spot-checks. Please address the following:
(1) Add a comparison of measured source output against calculated source output for that date in the gamma knife computer system.
(2) Indicate that timer accuracy and linearity are to be checked over the range of use.
(3) In order to make future inspections easier for both the inspector and you, you may want to consider using the same terminology as 10 CFR 35.645(c) and (d) when naming your spot-checks (i.e., instead of "alignment", use "trunnion centricity").

b) RSO policy 36-05, item 4) lists spot-check procedures. Please make the following updates:
(1) Rename procedures to make them consistent with the names used in RSO policy 36-04, or, at minimum, correlate them by number.
(2) Add procedures so that one is provided for each item required by 10 CFR 35.645(c) and (d). It appears that the following monthly check procedures may need to be added: treatment table retraction on backup, stereotactic frames and localizing devices, and on-off error.
(3) Regarding timer linearity and accuracy over the range of use, as well as on-off error, your monthly spot-check form references "linearity curves", but your procedure only references a check at 60 minutes and a check at 1 minute. Also, the tolerances shown on your form are different from the tolerances in your procedure. Please consider a 3 point test, and detail the method for evaluating linearity and on-off error (end effect).
(4) For daily checks, add procedures for check of electrical door interlocks and timer termination.

(5) Provide the procedure for the APS QA test.

c) For the Daily Startup Procedure form, update to include each of the 6 items listed in 10 CFR 35.645(d). Rename procedures to make them consistent with the names used in RSO policies 36-04 and 36-05. It appears that you may need to add the following: check of source exposure indicator lights on the gamma knife unit and control console and timer termination. It's also unclear if your "emergency stops" checks include an actual test of the emergency off button.

d) For the Gamma Knife Monthly Checks form, update to include each of the items listed in 10 CFR 35.645(c). Rename procedures to make them consistent with the names used in RSO policies 36-04 and 36-05. It appears that you may need to add the following: treatment table retraction on backup, emergency timing circuits, record of the result of the source output measurement, comparison of source output measurement with anticipated output, and comparison of source output measurement with gamma knife computer calculation. You should also keep some record of the measured data and data evaluation for source output measurement, comparisons of source output measurement with anticipated and computer values, and timer accuracy/linearity/on-off error.

e) We did not perform a detailed review of the Gamma Knife Annual Calibration form, as this is not required to be submitted. We did note that the form seems to allow for the tests to be performed by someone other than the Authorized Medical Physicist (AMP). Please note that the although the regulations allow spot-checks to be performed by someone else, then reviewed by the AMP, it is necessary for annual calibrations to be done by the AMP. It also appears that this form may not include all tests required by 10 CFR 35.635. Please assure that all of the required tests are performed. This information will be reviewed during inspections. No response to this item is required.

3) On page 3, RSO policy 36-01 addresses "Installation and Replacement of Sources" and "Maintenance and Repair of Device." Both sections state that work shall be performed only by persons specifically authorized and trained by the device manufacturer and, in the case of installation/replacement, the distributor. Please note that 10 CFR 35.605 states that only a person specifically licensed by the NRC or an Agreement State may perform these tasks. Please confirm that you will update your policy to reflect this requirement. It is not necessary to resubmit RSO policy 36-01, as long as you agree to make the update.

4) On page 4, RSO policy 36-01 addresses "Dosimetry Equipment Calibration and Checks." Item .04 lists the times at which full calibration checks shall be performed on the gamma knife unit. Please note that 10 CFR 35.635(a) also requires full calibration measurements to be performed whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration, corrected mathematically for radioactive decay. Please confirm that you will update your policy to reflect this requirement. Again, it is not necessary to resubmit RSO policy 36-01.

Please revise and resubmit RSO policies 36-03, 36-04, and 36-05, as well as the forms for Daily Startup Checks and Monthly Checks, in accordance with the changes requested above in Items 1) and 2). We will need to work very quickly in order to meet your time frame for first patient treatments. I will be in the office all day Thursday and Friday afternoon. I am not scheduled to be back in the office again before my trip next week. Please contact me to discuss your schedule for resubmission of procedures.

As always, you may fax your response to 610-337-5269, this time referencing mail control 138887. Please 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.

Thank you for your help.

Sandy Gabriel
Senior Health Physicist
Medical Branch
NRC Region I

CC: Harold Prussia

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