From: Sandra Gabriel
To: Alan Aqualino
Date: Wed, Jul 25, 2007 5:57 PM
Subject: Additional information for NRC license amendment request, mail control 140330

Licensee: University of Virginia
License No.: 45-00034-30
Docket No.: 03003067
Mail Control: 140330

To: Alan Aqualino, Ph.D., RSO

This is to follow up to our earlier discussions. In order to authorize your program for clinical use of the Perfexion gamma knife, please provide the following information within 30 days.

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

If your response includes sensitive security-related information such as quantities and locations of radioactive materials, please mark them as specified in Regulatory Issues Summary 2005-31, available at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf

1. Name the proposed authorized user(s) and authorized medical physicist(s), and provide documentation that they meet the requirements identified in the Perfexion licensing guidance. For example, for an AU currently authorized on an NRC or Agreement State license for gamma stereotactic radiosurgery (GSR) use under 10 CFR 35.600, document their current license status, their training in Perfexion device operation, safety procedures, and clinical use, and in the differences from the other GSR unit(s) for which they are authorized. For an AMP currently authorized on an NRC or Agreement State license for GSR use, document their current license status, their training in Perfexion hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system, and in the differences from the other GSR unit(s) for which they are authorized. Training documentation should include a detailed description of topics covered, the qualifications of the training provider(s), and a training certificate or signed statement from the training provider(s).

2. Confirm each of the following items for Perfexion GSR use:

a) Your written directive will include the patient's name, the total dose, the treatment site, and the values for the target coordinate settings and sector settings for each treatment shot within an anatomically distinct treatment area.

b) Your written procedures to provide high confidence that each administration is in accordance with the written directive will include:
i) verifying that any computer-generated dose calculations (including target coordinate and sector settings) are correctly transferred into the Perfexion console,
ii) pausing treatment and checking the patient set-up if a patient is observed to move during the course of a treatment shot, and
iii) visually checking the patient set-up each time the gamma angle is changed or at the end of the treatment run, whichever comes first.

c) You will meet the following requirements for a GSR unit in 10 CFR Part 35, Subpart H: 35.600, 35.605 (and retain records of the information described in 35.2605 for the period stated in 35.2605), 35.610 (and retain procedures described in 35.610(a)(4) and (d)(2) for the period stated in 35.2610), 35.615, 35.630 (and retain a copy of the information described in 35.2630 for the period stated in 35.2630), 35.635 (with modifications discussed below and retain a copy of the information described in 35.2632 with modifications discussed below for the period stated in 35.2632), 35.645 (with modifications discussed below and retain a copy of the information

described in 35.2645 with modifications discussed below for the period stated in 35.2645), and 35.657.

d) You will follow the survey requirement of 10 CFR 35.652 and make the surveys unit at installation of a new source and following repairs to the source shielding, sector drive unit, or other mechanical components that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or source(s). You will retain the information described in 35.2652 for the period stated in 35.2652.

e) You will follow the full calibration requirements of 10 CFR 35.635 and the spot-check requirements of 35.645 and retain the information described in 35.2632 for each full calibration and 35.2645 for each spot-check, except for those involving helmets, helmet factors, helmet microswitches, trunnions, hydraulic backup of the treatment table retraction system, or source exposure indicator lights on the unit. You will keep each record of full calibration and spot-checks for 3 years.

f) Before each patient use, you will confirm that the frame adapter is functioning correctly and can be attached correctly to the coordinate frame. The test and description of the record of the test will be included in your spot-check procedures. You will also perform this test during full calibration measurements. You will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.

g) Before the first use of the Perfexion unit each day, you will confirm that the docking device is securely mounted to the table and that the frame adapter can be correctly docked in the docking device. The test and description of the record of the test will be included in your spot-check procedures. You will also perform this test during full calibration measurements. You will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.

h) Before the first use of the Perfexion unit each day, you will confirm proper functioning of the source exposure indicator on the treatment room wall (or mounted from the ceiling). This test and the description of the record of the test will be included in your spot-check procedures. You will also perform this test during full calibration measurements. You will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.

i) On a monthly basis, you will confirm that the location of the radiation focal point, with respect to the table position, is within the specifications provided by the manufacturer. This test and the description of the record of the test will be included in your spot-check procedures. You will also perform this test during full calibration measurements. You will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.

j) On a monthly basis, you will confirm that the location of the table at a number of off-center positions is within the collision specifications provided by the manufacturer. This test and the description of the record of the test will be included in your spot-check procedures. You will also perform this test during full calibration measurements. You will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.

k) Approximately every six months (with exact date subject to vendor service availability), you will confirm that each sector moves correctly to each position within appropriate tolerance limits. This test and the description of the record of the test will be included in your spot-check procedures. You will also perform this test during full calibration measurements. You will keep each record of the results of this test performed during the full calibration measurement and spot-check for 3 years.

l) If the frame adapter fails to perform as designed, you will remove it from service until

repaired.

m) If the docking device, sector location, sector movement, or table positioning fail to perform as designed, you will lock the control console in the off position and not use the unit, except as necessary to repair, replace, or check the malfunctioning system.

n) If either the clearance test tool or QA test tool fail to function as specified by the manufacturer, you will have the tool repaired or replaced before the next patient treatment requiring proper functioning of that tool.

o) You will consider removal or major repair of components associated with the sector assemblies to be a major repair of the source assembly and will require full calibration.

p) You will perform full calibration measurement procedures in accordance with published protocols accepted by nationally recognized bodies, except when nationally recognized bodies have not published required full calibration procedures for components and features of the Perfexion unit. In the absence of published protocols for the Perfexion unit accepted by nationally recognized bodies, we will use procedures developed by the manufacturer.

q) You commit to have the Perfexion unit fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism. This inspection and servicing will be performed by persons specifically licensed to do so by the Commission or an Agreement State. You will retain records of the information described in 10 CFR 35.2655 for the period stated in 35.2655.

3. Provide a copy of your updated spot-check procedures for the Perfexion GSR unit, including all applicable checks required in 10 CFR 35.645, as well as those described in items 2f) through k) above.

4. Confirm that you will add to your emergency procedures the following additional items required by 10 CFR 35.610(a)(4):

a) the names of the individuals responsible for implementing corrective actions,

b) the names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally, and

c) procedures that you will use in an emergency (if applicable) to restrict access to the treatment room and alert others that they should not enter.

5. Describe the Perfexion emergency response equipment (if you wish, you may submit a copy of section 1.4.3 of the Perfexion IFU).

6. If you wish, you may request authorization to allow future revisions to your Perfexion GSR radiation safety program in accordance with any future changes in NRC's published Perfexion licensing guidance, and without a license amendment, by committing to the following conditions:

a) The revision will be in compliance with the regulations of the NRC or Agreement State (as applicable);

b) The revision is based on the current guidance for the Perfexion GSR unit 35.1000 use posted on the NRC website;

c) The revision has been reviewed and approved by your RSO and management;

d) The affected individuals are instructed on the revised program before the change in

implemented;

e) You will retain a record of each change for 5 years; and

f) The record will include a copy of the appropriate website guidance, your old procedure, your new procedure, the effective date of the change, and the signature of your management representative that reviewed and approved the change.

7. Confirm that non-human research will be performed under the direct supervision and physical presence of a Perfexion AMP or AU, or propose an alternative.

8. Describe the method you will use to assure that the Perfexion console key is inaccessible to unauthorized persons.

9. Indicate the location in the Perfexion treatment room of the area radiation monitor and the intended location of the radiation warning indicator.

10. Confirm that the door to the Perfexion treatment room will be posted with "Caution-Radioactive Materials" and "Caution-Radiation Area" signs.

Please note that you may not provide an official reply to this message by return e-mail. You may reply to my attention, referencing mail control 140330. The reply must be signed by a member of senior management and submitted in writing by letter or fax (610-337-5269). If a fax is sent, you may wish to alert me by e-mail or voicemail so that I will know to retrieve it.

Thank you for your help. If you have any questions, you may e-mail me or call at 610-337-5182. I will be out of the office from July 26-30 and August 7-8, however I will check voicemail messages daily and e-mail messages when feasible.

Sandy Gabriel
Senior Health Physicist
Medical Branch
NRC Region I
610-337-5182 (voice)
610-337-5269 (fax)

Mail Envelope Properties (46A7C763.A1C : 8 : 27167)

Subject:	Additional information for NRC license amendment request, mail control 140330
Creation Date	Wed, Jul 25, 2007 5:57 PM
From:	Sandra Gabriel
Created By:	SLG2@nrc.gov

Recipients
cms.mail.virginia.edu
aa2h (Alan Aqualino)

Post Office	**Route**
	cms.mail.virginia.edu

Files	**Size**	**Date & Time**
MESSAGE	15221	Wednesday, July 25, 2007 5:57 PM

Options

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