COLLEEN CAROL CASEY MATERIALS LICENSING BRANCH UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2443 WARRENVILLE ROAD STE 210 LISLE, ILLINOIS 60532-4352

OFFICE: (630)-829-9841 FAX: (630) 829-9782 or (630) 515-1259

CONVERSATION RECORD	TIME	DATE
ACTUALLY FAXED? YES.		August 3, 2005
NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Martin W. Johnson, M.S., RSO	517-364-2167	

SUBJECT

License No.: 21-01430-01

Control No.: 314456

SUMMARY

We have reviewed your letter dated May 3, 2005, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

10 CFR 35.961c is the regulation you used to is the regulation you used to prepare this application for Tracy King-Maudrie, M.S. as an AMP, which reads, in part:

"The licensee shall require the authorized medical physicist to be an individual who--

(c) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed 1 year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.632, 35.633, 35.635, 35.642, 35.643, 35.644, 35.645 and 35.652, as applicable."

I am unable to approve Ms. King-Maudrie's application to become an AMP at this time because the letter dated May 3, 2005, is insufficient to complete my review. Please address the following and resubmit the application at a later date, referencing control number 314456 to ensure appropriate handling:

- 1. <u>Please specify</u> exactly what you want Ms. King-Maudrie to become an AMP for. It is unclear what Ms. King-Maudrie is applying to be named an AMP for. Note that we do not name AMP's for radiopharmaceutical therapy, consulting services, or manual brachytherapy (except for strontium-90 ophthalmic applicators).
 - Further, it is my understanding the Guidant Galileo intravascular brachytherapy modality is obsolete and that the Novoste intravascular brachytherapy modality will be obsolete by the end of 2005. Therefore, it appears that Ms. King-Maudrie's application to become an AMP may be limited to HDR remote afterloading brachytherapy activities under this license only. Please advise us of your decision.
- 2. 10 CFR 35.961c clearly requires 1 year of full time training in therapeutic radiological physics and an additional year of full time work experience. Please note that this training and experience cannot be accounted for concurrently with training and

experience obtained in the course of studying for a degree. Therefore, the work Ms. King-Maudrie claims under Colin Ortin, at WSU cannot be counted toward compliance with this requirement.

In addition, the two year total of full time training and experience amounts to an equivalent of about 4160 hours (2080 hours per year times 2 years). Ms. King-Maudrie claims 1881 hours from August 2003 through May 3, 2005. Assuming (2080 divided by 12 months or 173 hours per month) times 3 months (May 2005 to today, August 3, 2005), adds ~520 hours. 1881 plus 520 = 2401 hours, which is well under the 4160 full time hours required. When Ms. King-Maudrie has completed an additional 1759 hours or more of full time training and experience, as required by 10 CFR 35.961c above, you may resubmit her application to become an AMP.

Please also note that a new rulemaking became effective April 29, 2005, which may affect Ms. King-Maudrie's future re-application, as it changes many key elements in the training and experience criteria in Part 35. More information on this rule should have been sent to you already and is available on our website. If you have further questions concerning these matters please contact me at (630) 829-9841 or (800) 522-3025.

3. The terminology NRC used in the regulation is deliberate and specific in its meaning. Your application uses other terms, such as "new source quality assurance testing," instead of, I assume(?), "full calibrations;" you refer to "monthly quality assurance testing" instead of, I assume(?), "periodic spot checks."

Please revise your application to use NRC terminology, as appropriate **OR** define what is meant by your use of the terms mentioned in the paragraph above and explain their equivalence to the NRC-required terminology.

4. It is not clear from Ms. King-Maudrie's application that she meets the requirements in 10 CFR 35.961c with respect to the types of work experience and training she has obtained. 10 CFR 35.961c requires work experience and training in 10 CFr 35.67, 35.633, 35.643 and 35.652.

Please review these requirements carefully and revise Ms. King-Maudrie's preceptor forms, as appropriate, to reflect her specific training and work experience in each of these required areas.

- 5. If Ms. King-Maudrie 's attestation statements show that more than one individual served as her preceptor <u>please submit</u> appropriate attestation statements prepared, signed and dated by each preceptor also. (See Part II—Preceptor Attestation Note on the forms you already submitted, which states this requirement).
- 6. <u>Please also provide</u> sufficient information for us to verify that each preceptor was qualified to serve as a preceptor AMP for Ms. King-Maudrie for the modalities she was supervised for and during the timeframes when she received supervised training and experience.
- 7. Please note that only training and experience, including vendor training and experience, that is relevant to this license's devices and activities, should be submitted for Ms. King-Maudrie. For example, work she has done in nuclear medicine and consulting, etc. is

irrelevant for the purposes of naming her as an AMP on this license. This is a no response item, for information only.

8. Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc. Please do not submit extraneous documents, including but not limited to, certificates received for attendance at meetings, conferences, continuing education and training sessions that are not relevant to the practice of therapeutic medical physics and the radiation therapy modalities covered by this license that require an AMP.

Please refrain from listing specialty certification board credentials that NRC does not recognize. Specialty board certifications that NRC does recognize are currently listed in 10 CFR Subpart J, until October 24, 2005, and on our website at http://www.nrc.gov. This is a "no response" required item.

- 9. Please refer to the above regulatory requirements as well as section 8.11, item 7 and Appendices B, D and E in **NUREG 1556, Vol. 9, Rev. 1**, for assistance in preparing your response. This is a "no response" required item.
- 10. Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects." Please focus on the regulatory requirements and only the information required to demonstrate compliance with the regulatory requirements. This is a "no response" required item.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

ACTION REQUIRED

As I am unable to issue an amendment to your license at this time, please submit the requested information at your convenience by referencing control number **314456** to facilitate proper handling. I am voiding your amendment request at this time, which is done without prejudice to the resubmission of your request at a later date. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address. PLEASE NOTE THAT A "VOID" IS AN ADMINISTRATIVE PROCEDURE THAT PUTS YOUR AMENDMENT REQUEST "ON HOLD" (TAKES IT OUT OF OUR ACTIVE CASEWORK DATABASE) UNTIL YOU REACTIVATE IT VIA A WRITTEN RESPONSE.

PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT (630) 829-9841 or (800) 522-3025.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Carol Casey	Colleen Carol Casey	August 3, 2005

NRC FORM 386 (RIII) (4-2004)



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION III

2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE:	8/3/05	NUMBER OF PAGES: (including this page)	4			
SEND TO:	MARTIN	JOHNSON, M.S.				
LOCATION:	EDWARD SPA	RROW HOSPITAL				
FAX NUMBE	R: 517-364-298	VERIFY BY CAL	LING SENDER			
FROM: (SENDER)	COLLEEN C	CHROL CASEY				
TELEPHONE NUMBER: 630 -829 - 984/ FAX NUMBER: 630 -829 - 978 2						
If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.						
MESSAGE	Call me of you h	ave quations. Ollen Carol Case	y			

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