## **CONVERSATION RECORD**

## 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) 515-1078 EMAIL: COLLEEN.CASEY@NRC.GOV

	ITIME	DATE
ACTUALLY FAXED / EMAILED? YES.		September 26, 2012
Fax No.: 407-455-6732		
Email address: bnelson@triadisotopes	.com	
NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Brigette Nelson, PharmD, Sr. Director, Quality and Safety	Triad Isotopes, Inc.	904-834-2086
SUBJECT		
License No.: 09-32781-03MD	Control No.: 577837	

SUMMARY

We have reviewed your letter dated June 26, 2012, 2012, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. In order for us to approve changes in Radiation Safety Officers (RSOs) for our "non-medical/non-10 CFR Part 35" licenses, it is necessary for the proposed RSO to sign a currently dated acknowledgment letter attesting that s/he agrees to become the RSO for the license in question and s/he understands the duties and responsibilities involved.

Our 10 CFR Part 35 licensees must comply with 10 CFR 35.24(b).

<u>Please provide</u> a currently dated acknowledgment letter attesting that Robert Bjurstrom, PharmD agrees to become the RSO for the license in question and he understands the duties and responsibilities involved.

In the alternative, Dr. Bjurstrom may call me or leave a voicemail message for me at (630) 829-9841 stating that he agrees to become the RSO for this license and he understands the duties and responsibilities involved.

- 2. Please also advise us as to whether the incumbent RSO on this license. Michael Klug, R.Ph. should remain on this license as an Authorized Nuclear Pharmacist or not. Also, has Mr. Klug been serving as RSO since this letter was submitted?
- 3. This is a "no response" item, just information only:

Your letter dated June 26, 2012, requested an expedited review. However, no information was provided to support this request. For future reference, please provide the following information when you feel it is necessary to request an expedited review:

Please contact us by telephone if an emergent situation arises before or after submitting an amendment request to your license to enable us to understand your circumstances, ensure our management is aware of your needs and work with you better to meet them. Please also justify and support the need for that particular amendment to be handled as an expedited request so our management can direct the case to an appropriate reviewer and assist you, as best we are able.

Ideally, if you know of an emergent situation impacting your license and you need an amendment by a certain specific date (not "stat" or "as soon as possible." etc.). please advise us of the situation, the specific date when the amendment is needed and the justification and support for your request for expedited processing, which should be briefly summarized.

Please also ensure that an appropriate senior management official and/or your Radiation Safety Officer signs and dates the amendment request letter.

Please include the name of a knowledgeable contact person who is familiar with your amendment request, his or her direct telephone number, and the best fax number to transmit the completed amendment to you. Including the contact's email address may also prove to be very helpful in these cases.

If you have any questions or comments concerning this amendment please contact me at either (800) 829-9500, ext. 9841 or (630) 829-9841. My fax number is (630) 515-1078.

We thank you in advance for your understanding, patience and cooperation.

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."

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this record will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

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## ACTION REQUIRED

Submit the requested information within **5 calendar days (by October 2, 2012)** by referencing control number **577837** to facilitate proper handling in our office. Please contact me if you need to make alternative response arrangements.

If we do not receive an adequate response by this date, we may partially issue the requested amendment changing the mailing address only, until we receive the information needed for Mr. Bjurstrom. Upon receipt of your response we will resume our review. Address your written response, via an appropriately dated and signed (by management) cover letter, to my attention at the above address.

## PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT 630-829-9841 or 800-522-3025, ext. 9841.

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NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE olleen Carol Casey

DATE

September 26, 2012

**Colleen Carol Casey**