



September 11, 2015

Ms. Jennifer Bishop
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4351

RE: NRC License number 13-18543-01 Renewal Application, Control Number 586452, Docket Number 030-13850

Dear Ms. Bishop:

This correspondence is in response to your "Conversation Record" (NRC FORM 699) dated September 10, 2015 related to a telephone conversation you had with Ms. Iwona Llorico and Ms. Lisha Combs on that date. In that conversation and record, you requested addition information and/or clarification on four (4) specific items in the above-reference license renewal application. Those items and the responses to same are as follows:

Item 1 - "In your application, you did not include a request to continue using byproduct materials permitted by 10 CFR 31.11. Please respond in writing if this authorization should continue to be included in your license."

Response to Item 1 - There is no intent to utilize byproduct materials permitted by 10 CFR 31.11; therefore, there is no need to include the use of those byproduct materials under this license.

Item 2 - "Please confirm in writing if you will be using PET radionuclides. If you will be using PET materials, please provide shielding calculations for areas where the materials will be used and stored."

Response to Item 2 - There is no intent to use PET radionuclides under this license at the present time. If that changes, an amendment will be submitted to the NRC including shielding calculations for areas where the materials will be used and stored.

Item 3 - "On your current license you have Dr. Benny Sin-Ping Ko, M.D. listed an authorized user, however, this was not included in your license renewal application. Please confirm in writing if Dr. Ko, M.D should continue to be listed on your license."

Response to Item 3 - Dr. Benny Sin-Ping Ko, MD should no longer be listed as an authorized user under this license.

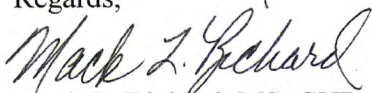
Item 4 - In your application, you included a commitment to perform area surveys, however the regulations referenced were incorrect. Please respond with the following: "We have developed and will

implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

Response to Item 4 – As you pointed out, there was an incorrect reference to the NRC regulations – 10 CFR 20.1301 should have read 10 CFR 20.1501. However, the reference to 10 CFR 35.70 was intentionally omitted because that section of the regulations only refers to surveys required following the administration of a radiopharmaceutical that requires a written directive. Inasmuch as this license only covers radiopharmaceuticals authorized under 10 CFR 35.100 and 10 CFR 35.200 and there is no intent to administer radiopharmaceuticals for diagnostic purposes that would require a written directive (e.g. greater than 30 microcuries of ¹³¹I), there is no need to include a reference to that section of the regulations in this statement. In order to correct the error, please see the attached revised version of the responses to Items, 5 through 11 from the original license renewal application with the corrected information included in the appropriate location and highlighted in red. Note that the original NRC Form 313 and Attachments 1 and 2 to the original renewal application haven't changed, so they aren't included in the attached revision. Please destroy the initial responses to Items 5 through 11 and replace them with the attached revised version.

Should you have any additional questions regarding the renewal application or this response, please don't hesitate to contact me at (317) 274-0330.

Regards,



Mack L. Richard, MS, CHP
Radiation Safety Officer
Community Westview Hospital

Attachments: 1

Cc: Iwona Llorico
Lisha Combs

License Renewal Application
NRC License No. 13-18543-01
March 23, 2015

Revised, September 11, 2015 in Response to NRC FORM 699 CONVERSATION RECORD
Dated September 10, 2015

Item 5
Radioactive Material

<u>A. Byproduct Material</u>	<u>B. Chemical/Physical Form</u>	<u>C. Maximum Amount</u>
Any byproduct material permitted by 10 CFR 35.100	Any	As Needed
Any byproduct material permitted by 10 CFR 35.200	Any	As Needed

Item 6
Purpose(s) for Which Licensed Material Will Be Used

10 CFR 35.100 – Medical use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

10 CFR 35.200 – Medical use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Item 7
Individual(s) Responsible for Radiation Safety Program
And Their Training and Experience

David C. Williams, D.O. – Dr. Williams is currently approved as an Authorized User on this NRC license.

Charles L. Walker, D.O. – See attached documentation (Attachment 1) of Dr. Walker's being authorized on page four (4) of a State of Wisconsin Radioactive Materials License.

Mack L. Richard, MS, CHP – Mr. Richard is currently approved as the Radiation Safety Officer (RSO) on this NRC license.

Item 8
Training for Individuals Working In or Frequenting Restricted Areas

Individuals who will be working in restricted areas (typically Nuclear Medicine Technologists working in the nuclear medicine laboratory and imaging areas) will be trained and instructed in accordance with 10 CFR 19.12.

Item 9
Facilities and Equipment

Facility Diagram

A facility diagram is attached (Attachment 2) with annotations including the use of each area within the restricted areas, the use of each area immediately surrounding the restricted areas, and the relative position of equipment within the restricted area.

Radiation Survey & Measuring Equipment

A portable, GM survey meter is utilized for routine radiation surveys of areas, personnel, and incoming shipments of radiopharmaceuticals. This survey meter is calibrated at least annually by a person qualified to perform survey meter calibrations.

A NaI well counter, connected to a multichannel analyzer is utilized for counting wipe test samples performed to verify compliance with 10 CFR 20 and 10 CFR 35 regulations. This counting system is efficiency calibrated at least annually utilizing rod sources covered under 10 CFR 35.65.

Even though radiopharmaceuticals are procured as unit doses, the licensee continues to possess and utilize a dose calibrator to assay patient doses prior to administration. That dose calibrator will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

The licensee reserves the right to upgrade or obtain a substitute for any of the aforementioned equipment as necessary, provided that such upgrades or substitutions are adequate to measure the type and level of radiation or activity for which they are used.

Item 10
Radiation Safety Program

Safety Procedures & Instructions

As indicated in Item 8, instructions and training are provided in accordance with 10 CFR 19.12.

Occupational Dose

The licensee will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or will provide dosimetry that meets the requirements listed under Section 8.23, Item 10: Occupational Dose, "Criteria" in NUREG-1556, Vol. 9, Rev. 2 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated January 2008.

Area Surveys

The licensee has developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 and ~~10 CFR 20.1301~~ 10 CFR 20.1501.

Safe Use of Unsealed Licensed Material

The licensee has developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

Spill Procedures

The licensee has developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.

Item 11 Waste Management

The licensee has developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92.

Dalzell-Bishop, Jennifer

From: Combs, Lisha <LCombs@ecommunity.com>
Sent: Friday, September 11, 2015 1:07 PM
To: Dalzell-Bishop, Jennifer; Llorico, Iwona
Subject: [External_Sender] RE: Transmittal of Conversation Record
Attachments: NRC Conversation Record Response.pdf

Attached is our response to the review of our NRC license renewal. Let me know if you have any other questions/concerns.



Lisha Combs, BS, CNMT
Nuclear Medicine Technologist
Medical Imaging Services
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O: 317.920.7184
LCombs@ecommunity.com

From: Dalzell-Bishop, Jennifer [mailto:Jennifer.Dalzell-Bishop@nrc.gov]
Sent: Thursday, September 10, 2015 11:34 AM
To: Llorico, Iwona; Combs, Lisha
Subject: Transmittal of Conversation Record

Dear Ms. Combs,

Attached is the conversation record regarding the additional information needed to complete our review of the NRC license renewal application for Community Westview Hospital. Please send in your response by fax or email, with a signed cover letter, to 630-515-1078 or Jennifer.Dalzell-Bishop@nrc.gov.

Please to contact me if you have additional questions.

Sincerely,

Jennifer Bishop
Health Physicist

U.S. Nuclear Regulatory Commission, Region III
Division of Nuclear Materials Safety
Materials Licensing Branch
Jennifer.Dalzell-Bishop@nrc.gov
630-829-9607 (Office)

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