Gryglak, Magdalena

From: Gryglak, Magdalena
Sent: Tuesday, January 22, 2019 10:01 AM
To: zszhang6@yahoo.com
Subject: FW: Renewal of NRC License no. 13-32700-01
Attachments: Request for Additional Information, CN 609964.docx

From: Gryglak, Magdalena
Sent: Friday, January 18, 2019 11:06 AM
To: zzhang@ohaev.com
Cc: Frazier, Cassandra <Cassandra.Frazier@nrc.gov>
Subject: Renewal of NRC License no. 13-32700-01

Mr. Zhang;

I have reviewed the information you provided in support of your renewal of NRC License no. 13-32700-01. Unfortunately, there is information missing from the application that NRC requires in order to renew a license.

Please see the attached document regarding the required information.

I would like to discuss with you the content to the attached document to ensure your thorough understanding of the information. Please acknowledge the receipt of this email. Also, please let me know if January 22, 2019 will work to discuss the additional information needed.

Thank you

Magdalena R. Gryglak
U.S. NRC Region III
630-829-9875

NRC FORM 699
(11-2017)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
Zhongshan Zhang, M.Sc.	01/22/2019	☐ E-MAIL ☑ TELEPHONE ☐ INCOMING ☑ OUTGOING
E-MAIL ADDRESS zzhang@ohaev.com	**TELEPHONE NUMBER** 812-490-5179	
ORGANIZATION Oncology Hematology Associates of S.W. Indiana	**DOCKET NUMBER(S)** 030-37836	
LICENSE NAME AND NUMBER(S) Oncology Hematology Associates of S.W. Indiana 13-32700-01	**MAIL CONTROL NUMBER(S)** 609964	

SUBJECT
Request for Additional Information

SUMMARY AND ACTION REQUIRED (IF ANY)

On 1/22/19, M. Gryglak, C. Frazier and Z. Zhang discussed the additional information as summarized below. (see the next page).

NAME OF PERSON DOCUMENTING CONVERSATION
MAGDALENA B. GRYGLAK

SIGNATURE
Magdalena B. Gryglak

DATE OF SIGNATURE
1/22/19

In order to continue our review of your renewal, I need additional information. Please refer to NUREG 1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses," which is accessible at https://www.nrc.gov/docs/ML0734/ML073400289.pdf, and Table C.3.

Please provide the following information:

A. For 10 CFR 35.200 material, provide the type of the material, chemical/physical form, the maximum amount, and the authorized use as it appears on the license.

B. For 10 CFR 35.500 material, confirm whether the authorized use is for diagnostic medical use (as it currently appears on the license) or for calibration of the PET/CT unit only which would fall under 10 CFR 35.65.

C. If 10 CFR 35.500 material is for medical use, please specify the manufacturer and model number/s of the 10 CFR 35.500 material (Ge/Ga-68 sources)

D. For 10 CFR 35.600 material, please confirm the following-

1. HDR unit:
Manufacturer name:
Model number:

2. Sealed Source:
Manufacturer name:
Model number:

E. Please specify the Ir-192 source activity at the time of medical use.

F. Provide the RSO Delegation of Authority Letter. A model letter can be found in Appendix I of NUREG 1556, Volume 9, Revision 2. Please ensure that the RSO and senior management official date and sign the letter.

G. Name the Authorized Medical Physicist.

H. Confirm the authorized use for the Authorized Users to be listed on your license.

I. Facility diagram-10 CFR 35.200/35.300/35.500 material:

1. Please provide diagram/s of all areas where 10 CFR 35.200 (F-18), 10 CFR 35.300 (I-131), and 35.500 materials are used and stored in accordance with guidance in NUREG 1556, Volume 9, Revision 9, Section 8.16, including:

a. Illustrate and label each room where radioactive material will be used and stored including the imaging room, injection/uptake rooms, hot lab, "quiet room", bathrooms, etc;
b. Provide the address on the diagram and show the direction of north
c. Clearly illustrate the room boundaries and door entries
d. Describe how the material is secured (i.e. locked door, locked storage cabinets etc)
e. Provide the room dimensions or scale for all rooms where radioactive material is stored
f. Illustrate on the diagram and describe all room/areas above, below, and adjacent to the rooms where radioactive material is used and stored
g. Illustrate on the diagram and describe areas inside the rooms where radioactive material is used or stored such as radioactive waste storage, material receipt area, work area, L-shield, sinks, fume hoods, etc.

J. Shielding evaluation- 10 CFR 35.200 material (PET)

1. Please provide simple and complete shielding calculations; show your work; explain assumptions; define terms, equations, constants, substitutions and parameters, to demonstrate that radiation levels in all adjacent areas, including above and below the rooms where the material is used will not exceed the levels in 10 CFR 35.1301 for members of the public and radiation workers.

Please clearly correlate all points for which dose levels are calculated with points on the diagram so corroboration is possible.

2. In your evaluation, describe the isotope used (F-18), the maximum activity used for F-18, uptake and scan times per patient, how many patients per day and how many days per week, and occupancy factors.

3. Describe the type of shielding material/barriers in each room for all adjacent areas, including above and below (i.e. poured concrete, lead etc.)

4. Provide thicknesses of the shielding material/barriers in each room for all adjacent areas, including above and below

5. Provide distances from the patient/exposed source to the adjacent areas/rooms which will be occupied in each direction, including above and below.

K. Facility Diagram- HDR treatment room

1. Please provide diagram/s (simple, hand-drawn diagrams are sufficient) that clearly show the proposed HDR treatment room and the location and functional identity of all adjacent rooms, areas and/or spaces surrounding it, including the areas above it and beneath it.

2. Please state the street address on the diagrams.

3. Provide the dimensions of the HDR treatment room or the scale.

4. Show the direction of north on the diagram

5. Show the functional identity of each room, space or area immediately surrounding the HDR room and whether they are restricted (R) or unrestricted areas (U) (see 10 CFR 20.1003 for definitions).

6. Show the elevation/grade clearly described and what space is above and below the HDR room; its functional identity and whether it is restricted (R) restricted (R) or unrestricted areas (U).

7. Indicate clearly on the diagram where you anticipate the patient/"exposed source" to be located within the room during treatments.

8. Show the location in the room where the HDR device will be stored.

9. For each barrier in each direction, including the floor and ceiling:

a. Describe the shielding material (poured concrete, lead etc.)

b. Provide the thicknesses of barriers.

c. Provide the distances from the patient/exposed source" to the adjacent rooms in all directions.

10. Please indicate clearly whether persons may gain access to any area adjacent to, above and below the HDR treatment room.

Are administrative controls in place to prevent access to the roof and/or any other potentially unrestricted areas during HDR exposures and treatments? Please describe.

If areas may be occupied during treatment, please either submit exposure rate calculations to demonstrate that the doses received will not exceed the limits in 10 CFR 20.1301 or describe the administrative controls (training, posting, surveillance, closed circuit television surveillance, lock-out, key control, etc.) that will be put in place to prevent occupation during HDR treatments or source exposures.

L. Shielding Evaluation-HDR treatment room:

1. Please provide simple and complete shielding calculations; showing your work, barrier transmission factors; explain assumptions; define terms, equations, constants, substitutions
and parameters to demonstrate that radiation levels in all adjacent areas, including above and below the room will not exceed the levels in 10 CFR 35.1301 for members of the public and radiation workers.

Please clearly correlate all points for which dose levels are calculated with points on the diagram so corroboration is possible.

2. Please include the following details in your calculations:

a. expected radiation levels for each adjacent area, under the most adverse and typical source orientations and maximum source activity at the time of medical use with shielding and distance factored in;

b. all parameters used to perform the calculations, including distance to each area of concern, the type and thickness of material(s) used as shields, especially if portable shields will be used;

c. the maximum "beam-on time" per hour and per week; the number of patients/treatments/exposures expected per week (i.e., workload);

d. state occupancy factors used for all adjacent areas, including areas above and below;

e. provide calculation of your transmission factor;

M. Radiation Monitoring Instruments:

Please provide required commitments for Radiation Monitoring Instruments as described in NUREG 1556, Volume 9, Revision 2, Section 8.17 and Table C.3.

N. Dose Calibrator and Other Dosage Measuring Equipment:

Please provide a required commitment for Dose Calibrator and Other Dosage Measuring Equipment as described in NUREG 1556, Volume 9, Revision 2, Section 8.18, and Table C.3.

O. Therapy Unit-Calibration and Use of HDR (Safety Procedures and Instructions in accordance with 10 CFR 35.643)

1. Please provide your procedures describing when and what spot checks will be performed in accordance with requirements in 10 CFR 35.643.

2. Please provide your procedures describing how the various spot checks will be performed in accordance with requirements in 10 CFR 35.643. Please note that in addition to listing the spot checks, your procedures need to briefly describe how each spot check will be performed. For example, to check whether the HDR room audio system works, you will turn the system on and have another authorized person enter the HDR room and you will communicate with the individual to ensure you can hear each other.

3. Please confirm that "if the results of the checks required in 10 CR 35.343(d) indicate the malfunction of any system, you will lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system."

P. Other equipment and Facilities (HDR treatment room). Please refer to NUREG 1556, Volume 9, Revision 2, Section 8.20:

1. Please describe how you will secure: a) the unit; b) the console; c) the console keys; d) and the treatment room when not in use or unattended in accordance with 10 CFR 35.610(a)(1). Describe who will have access to the unit, the console, the console keys, and the HDR treatment room (use specific terms such as RSO, AMP, RSO, etc.)

2. Please describe how you will control access to the HDR treatment room (e.g. describe physical barriers such as locked door, signs, alarms, warning lights, etc.)

3. Please confirm that only one radiation producing device will be operating at one time in the HDR room in accordance with 10 CFR 35.610(a)(3).

4. Please describe the design and the function of your electrical interlock system in accordance with 10 CFR 35.615(b).

5. Please describe your radiation monitoring equipment in the HDR treatment room in accordance with 10 CFR 35.615(c)

6. Please describe your viewing and communications systems to permit continues observation of the patient during treatment in accordance with 10 CFR 615(d).

7. Please provide a description of the emergency response equipment available near the treatment room to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment in accordance with 10 CFR 35.615 (g).

Q. Safety Procedures and Instructions in accordance with 10 CFR 35.610:

1. Please provide your emergency procedures and instructions to respond to abnormal situations associated with the use of the HDR unit. Please refer to NUREG 1556, Section 8.22 for guidance regarding the content of the procedures.

2. Please, ensure that you address all regulations in 10 CFR 35.610:

a. Describe how you will permit only individuals approved by the AU, RSO, or AMP to be present in the treatment room during treatment with the sources in accordance with 10 CFR 35.610(a)(2);

b. Name individuals responsible for implementing corrective actions after an abnormal situation in accordance with 10 CFR 35.610(4)(i);

c. Describe the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure in accordance with 10 CFR (a)(4)(ii);

d. Name and provide the telephone numbers of the AUs, the AMP, and the RSO to be contacted if the unit or console operates abnormally in accordance with 10 CFR 35.610(4)(iii);

e. Confirm that the operating instructions, the emergency procedures and the contact information for the AUs, AMP and RSO will be physically located at the unit console in accordance with 10 CFR 35.61099(b) and (c).

f. Confirm that operators, AMPs, and AUs will participate in drills of the emergency procedures, initially and at least annually, in accordance with 10 CFR 35.610(e).

R. Occupational Dose:

Please provide a required commitment for Occupational Dose as described in NUREG 1556, Volume 9, Revision 2, Section 8.23 and Table C.3.

S. Area Surveys:

Please provide the required commitment for Area Surveys as described in NUREG 1556, Volume 9, Revision 2, Section 8.24 and Table C.3.

T. Safe Use of Unsealed Licensed Material:

Please provide the required commitment for Safe Use of Unsealed Licensed Material as described in NUREG 1556, Volume 9, Revision 2, Section 8.25 and Table C.3.

U. Spill/Contamination Procedure:

Please provide the required commitment for Spill/Contamination Procedure as described in NUREG 1556, Volume 9, Revision 2, Section 8.26 and Table C.3.