

**From:** [Kelly Stoneberg](#)  
**To:** [Gallagher, Robert](#); [Hess, David F.](#); [Fernandez, John E.](#)  
**Cc:** [Israel, Jim](#)  
**Subject:** [External\_Sender] RE: United Hospital Center request for additional information  
**Date:** Monday, July 18, 2022 3:15:59 PM  
**Attachments:** [image002.png](#)  
[image003.png](#)  
[United Hospital Center \(47-01458-01\) RAI Response NRC Email 7-13-22.pdf](#)  
[United Hospital Center RSO Delegation of Authority.pdf](#)

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Hi Robert,

Attached is the response letter for your request for additional information as outlined in your email dated 7/13/22. Also attached is the Delegation of Authority documenting me as RSO. It is signed by the facility current senior management.

Please contact me with any questions or concerns.

C. Kelly Stoneberg



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(888) 456-5255

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**From:** Gallagher, Robert <Robert.Gallagher@nrc.gov>  
**Sent:** Wednesday, July 13, 2022 9:17 AM  
**To:** Hess, David F. <Hessd@wvumedicine.org>  
**Cc:** Kelly Stoneberg <kstoneberg@ohiomedphys.com>  
**Subject:** United Hospital Center request for additional information

License No. 47-01458-01  
Docket No. 03003375  
Control No. 631361

Mr. David Hess, President and Chief Executive Officer  
United Hospital Center

Dear Mr. Hess;

This is in reference to your letter dated July 11, 2022, requesting to amend NRC License No. 47-11458-01. In order to continue our review, we need the following additional information:

Section 8.7.1 Radiation Safety Officer (RSO) and Associate Radiation Safety Officers (ARSOs) of NUREG 1556, Vol. 9, Rev 3. Consolidated Guidance About Materials Licenses Program Specific Guidance About Medical Use Licenses, <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html> provides licensees information to submit relative to their requests for RSOs. Please provide the following:

a) Your request indicates that Mr. Stoneberg will have 1 – 1.5 hours per week to dedicate to the RSO responsibilities and your license includes authorizations for activities under 10 CFR 35.100, 200, 300, 400, and 600 (HDR). You have identified Yin Huang as the primary point of contact (POC), however you have not requested Yin Huang be added as ARSO. Given the extensive nature of your program, it is not likely that the radiation safety program will be successful with only 1 – 1.5 hours of on-site oversight per week. Please review the RSO responsibilities listed in Appendix I of the above referenced NUREG and provide a breakdown of what duties will be performed by your on-site POC under Mr. Stoneberg's direction. You may also add to the list if you have identified other tasks that support the higher-level tasks listed in the Appendix.

b) Please indicate how frequently the on-site representative will meet with Mr. Stoneberg to report on the status of their activities.

c) Please indicate whether the phone number provided for Mr. Stoneberg is personal information or publicly available information.

d) Please provide a written delegation of authority for Mr. Stoneberg to serve as Radiation Safety Officer signed by senior management.

We will continue our review upon receipt of this information. Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email (preferred option); or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail.

Please note that the Region I office is currently in the process of moving to 475 Allendale Road, King of Prussia, PA 19406, with the official move date to be determined. In the interim, if possible, please send all communications electronically to [R1DRSSMail.Resource@nrc.gov](mailto:R1DRSSMail.Resource@nrc.gov) with the mail control number referenced, or directly to me at [Robert.gallagher@nrc.gov](mailto:Robert.gallagher@nrc.gov). In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: [www.nrc.gov](http://www.nrc.gov). Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM). In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them. If you have any questions regarding this request for additional information, please contact me at (610) 337-5076 or via electronic mail at [Robert.gallagher@nrc.gov](mailto:Robert.gallagher@nrc.gov).

Thank you for your cooperation.

Sincerely,

Robert L. Gallagher  
Health Physicist  
Medical & Licensing Assistance Branch  
U.S. NRC, Region I  
2100 Renaissance Blvd.  
King of Prussia, PA 19406  
(610) 337-5182 office  
(610) 337-5269 fax



July 18, 2022

Licensing Assistance Team  
Division of Nuclear Materials Safety  
US Nuclear Regulatory Commission, Region I  
2100 Renaissance Boulevard, Suite 100  
King of Prussia, PA 19406-2713

Re: License Number 47-01458-01 – RAI Email Dated 7/13/22

Mr. Gallagher,

This letter is in response to your request for additional information detailed in your July 13, 2022, email. The order of responses is concurrent with your email.

- a. United Hospital Center will have two point of contact individuals on-site at the facility. Yin Huang, PhD, AMP will be the primary point of contact for matters concerning 35.300, 35.400 and 35.600 (HDR). Melissa Holtz, CNMT will be the primary point of contact for matters concerning 35.100, 35.200. Both will assist in overseeing these areas under Mr. Stoneberg's direction.

Below is the requested breakdown of duties performed based on NUREG 1556, Vol. 9, Rev 3., Appendix I.

- ***Stop activities involving licensed material that the radiation safety officer (RSO) considers unsafe.***  
Ms. Huang and Ms. Holtz will be on-site daily monitoring activities to ensure that the safe use of radioactive materials. Ms. Huang and Ms. Holtz will report any unsafe activities directly to Mr. Stoneberg via telephone or teleconference and confer with him for direction.
- ***Ensure that radiation exposures are kept as low as is reasonably achievable (ALARA).***  
Mr. Stoneberg will monitor and evaluate all dosimeters exposure reports and discuss any matters pertaining to the results with the Radiation Safety Committee at the quarterly meetings. This will include investigation of elevated readings and dose estimates. Our facility uses Landauer Inc. as our radiation dosimeter vendor. Mr. Stoneberg has full access to the Landauer "My LDR" on-line system which provides real time access of all personnel dosimetry readings.

- ***Oversee all activities involving radioactive material, including monitoring, and surveying all areas in which radioactive material is used or stored.***

Mr. Stoneberg will oversee all activities involving radioactive material, including monitoring, and surveying all areas in which radioactive material is used or stored, though the on-site points of contact. They will report directly to Mr. Stoneberg for instruction.

- ***Ensure that up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed, as appropriate.***

Mr. Stoneberg, along with the point of contacts and authorized users will ensure that up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed, as appropriate. These procedures will be reviewed quarterly for compliance with a formal documented review annually.

- ***An inventory of all radioactive material is maintained, as required. Ensure that possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the Sealed Source and Device (SSD) registration certificate(s), and the manufacturer's recommendations and instructions.***

All sealed sources will be inventoried, and leak tested (as appropriate) by Mr. Stoneberg, semi-annually in conjunction with his quarterly visits. Ms. Huang, HDR Authorized Medical, Physicist will oversee, on a daily basis, the HDR source and any 35.400 brachytherapy sources possessed or in use. Ms. Huang will report any issues regarding these sources directly to Mr. Stoneberg. Ms. Holtz, nuclear medicine technologist, will oversee all nuclear medicine sealed sources and unsealed material (including waste) used in nuclear medicine on a daily basis. Ms. Holtz will report any issues regarding these sources directly to Mr. Stoneberg.

- ***The receipt, opening, and delivery of all packages of radioactive material arriving at the facility are overseen and coordinated. Also, radiation surveys of all shipments arriving or leaving the facility, as well as packaging and labeling of radioactive material leaving the facility are overseen.***

All activities concerning the receipt, opening, and delivery of all packages of radioactive material arriving at the facility will be under the oversight of Ms. Holtz (nuclear medicine) and Ms. Huang (radiation therapy). Also, radiation surveys of all shipments arriving or leaving the facility, as well as packaging and labeling of radioactive material leaving the facility will be overseen on a daily basis by Ms. Holtz (nuclear medicine ) and Ms. Huang (radiation therapy). Ms. Holtz and Ms. Huang will report any issues regarding these activities directly to Mr. Stoneberg.

- ***Ensure individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license.***

Ms. Huang, Authorized Medical Physicist, will ensure individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license. Ms. Huang will report any issues regarding these activities directly to Mr. Stoneberg.

- ***Ensure personnel training is conducted and is commensurate with the individual's duties regarding licensed material.***

Mr. Stoneberg will ensure personnel training is conducted and is commensurate with the individual's duties regarding licensed material with assistance of the on-

site points of contact. The documentation of the training will be reviewed in conjunction with Mr. Stoneberg's quarterly visits.

- ***Ensure documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits or that personnel monitoring devices are provided.***

As stated above, Mr. Stoneberg will monitor and evaluate all dosimeters exposure reports and discuss any matters pertaining to the results with the Radiation Safety Committee at the quarterly meetings.

- ***When necessary, ensure personnel monitoring devices are used and exchanged at the proper intervals, and personnel radiation exposure and bioassay records are monitored, reviewed, and maintained. Individuals are notified when radiation exposures are approaching established limits and appropriate corrective actions are taken.***

When necessary, the on-site points of contact, along with Mr. Stoneberg, via the Landauer "My LDR" on-line system, will ensure personnel monitoring devices are used and exchanged at the proper intervals, and personnel radiation exposure and bioassay records are monitored, reviewed, and maintained. Individuals will be notified, by the on-site points of contact, in conjunction with the RSO and RSC, when radiation exposures are approaching established limits and appropriate corrective actions are taken.

- ***Properly secure radioactive material from unauthorized use or access.***

The security of all radioactive materials will be monitored on a daily basis by the on-site POC. The on-site POC will report any issues regarding these activities directly to Mr. Stoneberg.

- ***Ensure documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in 10 CFR 20.1301, "Dose limits for individual members of the public."***

Documentation is on file regarding "Dose limits for individual members of the public." Any needed changes, measurements or calculations will be coordinated with Mr. Stoneberg.

- ***Notify proper authorities of incidents, such as damage to or malfunction of sources/devices, excess breakthrough values for Mo-99/Tc-99m or Sr-82/Rb-82 generators, loss of licensed material, fire, theft.***

All notification of proper authorities regarding the above issues will be coordinated by Mr. Stoneberg with the assistance of the POC.

- ***Serve as a point of contact for the NRC's and licensee's management during routine operations, emergencies, or incidents.***

The POC, under the supervision of the Mr. Stoneberg, along with Mr. Stoneberg will serve as a point of contact for the NRC's and licensee's management during routine operations, emergencies, or incidents.

- ***Medical events and precursor events are investigated and reported to the NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken.***

The POC, under the supervision of the Mr. Stoneberg, along with Mr. Stoneberg will oversee that all medical events and precursor events are investigated and

reported to the NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken.

- ***Perform and document periodic audits, at least annually, of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license.***

Annual reviews of the radiation safety program will be performed by Mr. Stoneberg in conjunction with his quarterly visits. These reviews will be reviewed and signed by administration. Documentation of the reviews will be kept on file.

- ***Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.***

The POC will ensure that the audit results and corrective actions are communicated to all personnel who use licensed material. Any needed follow up will be coordinated with Mr. Stoneberg.

- ***When the licensee identifies violation(s) of regulations or license conditions or program weaknesses, ensure corrective action(s) are developed, implemented, and documented.***

All violations of regulations or license conditions or program weaknesses, will be overseen by Mr. Stoneberg with the assistance of the POC.

- ***Ensure that all incidents, accidents, and personnel exposure to radiation in excess of 10 CFR Part 20 and 10 CFR Part 30 limits are investigated, their cause(s) are identified, appropriate corrective action(s) are implemented, and reports are submitted to NRC and other appropriate authorities, if required, within the required time limits.***

As stated above, Mr. Stoneberg will monitor and evaluate all dosimeters exposure reports and discuss any matters pertaining to the results with the Radiation Safety Committee at the quarterly meetings. These will include identification of cause and corrective actions.

- ***Ensure that licensed material is transported, or offered for transport, in accordance with all applicable NRC and DOT requirements.***

Ms. Holtz will ensure that licensed material is transported, or offered for transport, in accordance with all applicable NRC and DOT requirements as regard material used in nuclear medicine. Ms. Huang will ensure that licensed material is transported, or offered for transport, in accordance with all applicable NRC and DOT requirements as regards material in 35.400 and 35.600. Both will report any issues directly to Mr. Stoneberg.

- ***Ensure that radioactive waste is disposed of in accordance with NRC regulations and license conditions. Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records. Oversee the storage of radioactive material not in current use, including waste.***

The only radioactive waste generated will be from nuclear medicine procedures. Ms. Holtz will oversee the radioactive waste program in nuclear medicine. She will report any issues with program directly to Mr. Stoneberg.

- ***Perform/oversee the inventory and leak testing on all sealed sources.***

As stated above, Mr. Stoneberg will perform all appropriate sealed source inventories and leak tests in conjunction with his quarterly visits.

- **Oversee the calibration of radiation survey instruments.**  
Our facility uses a third-party service for our radiation survey instruments. The POC will oversee the calibration of the units. The calibration program will be monitored by Mr. Stoneberg in conjunction with his quarterly audits.
  - **Supervise decontamination operations.**  
The POC will supervise decontamination operation, with the remote assistance of Mr. Stoneberg. Documentation of the operations will be reviewed by Mr. Stoneberg in conjunction with his quarterly audits.
  - **Maintain up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to the NRC during the licensing process.**  
Mr. Stoneberg will supervise and maintain all radioactive materials licensing activities.
  - **Submit amendment and renewal requests in a timely manner.**  
Mr. Stoneberg will supervise and maintain all radioactive materials licensing activities.
- b. The on-site point of contacts, Ms. Huang, and Ms. Holtz will meet in person, at a minimum of quarterly with Mr. Stoneberg in conjunction with the quarterly audits. That frequency of in-person meetings will be increased and adjusted as needed. Also, the Ms. Huang, Ms. Holtz will meet as needed via telephone and teleconference.
- c. Mr. Stoneberg's phone number is publicly available information.
- d. Attached is the RSO Delegation of Authority signed by Mr. Stoneberg and David Hess, senior administration.

Please contact our consultant, C. Kelly Stoneberg, at (888) 245-6672 or [kstoneberg@ohiomedphys.com](mailto:kstoneberg@ohiomedphys.com) with any questions or concerns.

Sincerely,



David F. Hess, M.D.  
President, United Hospital Center

Memo To: Radiation Safety Officer  
From: Administration  
Subject: Delegation of Authority

You, **C. Kelly Stoneberg** have been appointed Radiation Safety Officer at **WVU Medicine – United Hospital Center** in Bridgeport, WV and are responsible for ensuring the safe use of radioactive material. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations as justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the State at any time.

DAVID F. HESS, MD

Management Representative (Print Name)

David F. Hess, MD

Signature of Management Representative

Date 7/18/2022

I accept the above responsibilities,

C. Kelly Stoneberg

Signature of Radiation Safety Officer

Date 5/1/22