



TO: C. Durbin, Ph.D., RSO

COMPANY: St. Lukes Hosp. Radiology Dept.

NUCLEAR REGULATORY COMMISSION
REGION III
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CONVERSATION RECORD

NAME OF PERSON(S) CONTACTED	Telephone No.	ORGANIZATION	TIME	DATE
Christopher M. Durbin, Ph.D.	(314) 205-6218	St. Luke's Hospital Radiology Department	10:00 am	April 3 & 18, 2012
REPRESENTED PERSON or PERSONS		ORGANIZATION		
C. Durbin, Ph.D., Radiation Safety Officer		St. Luke's Hospital Radiology Department		
SUBJECT	License No.: 24-01570-03 Control No.: 576920			

SUMMARY

We have reviewed your license amendment request dated February 2, 2011, and find that we are unable to continue this action until we have received information regarding the following:

1. The request to add Amit Kirit Bhatt, M.D., included two separate NRC Form 313A (AUT) forms. To add Dr. Bhatt as an Authorized User, with an authorization to use radioactive materials permitted by 10 CFR 35.300, a preceptor attestation is required under 10 CFR 35.390(b)(2). The preceptor attestation should affirm that Dr. Bhatt has both complied with the classroom and laboratory (200 hours minimum) requirements indicated in 10 CFR 35.390(b)(1)(i), and the work experience requirements indicated in 10 CFR 35.390(b)(1)(ii). Note that the NRC requires additional documentation supporting Dr. Bhatt's completion of at least 3 cases for each 10 CFR 35.300 category requested, per the requirements described in 10 CFR 35.390(b)(1)(ii)(G). The supervising individual must be authorized for the same category of material for which Dr. Bhatt is seeking AU status. The preceptor Authorized User must also be authorized for the same dosage category or categories as those requested by Dr. Bhatt.
 - a. The NRC Forms 313A (AUT) indicate that Dr. Bhatt completed a total of 670 hours of classroom and laboratory training, which is inconsistent with information submitted on the NRC Form 313A (AUS); see below. The February 2, 2011, request included a letter dated January 11, 2012, signed by Kristin Bradley, M.D., which provided a generic confirmation of Dr. Bhatt's total training and experience hours. The letter was unclear as to whether Dr. Bradley was confirming the 670 hours listed on the NRC Form 313A (AUT) forms, or the 610 hours listed on the NRC Form 313A (AUS).

Please provide additional documentation specifically outlining the number of hours of classroom and laboratory training completed, meeting the requirements listed in 10 CFR 35.390(b)(1)(i). The documentation should clearly explain any discrepancy between hours listed on the NRC Form 313A (AUT) and the NRC Form 313A (AUS).

- b. The NRC Form 313A (AUT) signed by Dr. Bradley, indicates that, as a supervising individual, Dr. Bradley meets the requirements listed in 10 CFR 35.394, 10 CFR 35.396 (beta emitters and photon-emitting radionuclides with photon energies <150 keV), and 10 CFR 35.396 (photon-emitting radionuclides with photon energies > 150 keV). Supporting documentation is limited to Dr. Bradley's authorizations as of November 3, 2011. On that date, Dr. Bradley's authorizations do not include either 10 CFR 35.394 or 35.396 (photon-emitting radionuclides with photon energies > 150 keV).

The NRC Form 313A (AUT) signed by David Butler, M.D., indicates that Dr. Bhatt completed a total of 26 hours supervised work experience, which is inconsistent with the NRC Form 313A (AUT) signed by Dr. Bradley. As noted in the NRC Phone conversation record dated December 16, 2011, and recorded by NRC Health Physicist Dennis O'Dowd, "it is implicit in 10 CFR 35.390 that the individual undergoing training have approximately 500 hours of supervised work experience". The 26 hours listed on the NRC Form 313A (AUT) signed by Dr. Butler falls far short of this requirement. In addition, while Dr. Butler is an Authorized User for the full spectrum of 10 CFR 35.300 material, the NRC Form 313A (AUT) signed by Dr. Butler limits supervised clinical case experience to cases related to the oral administration of sodium iodide I-131.

Please resubmit one NRC Form 313A (AUT) for Dr. Bhatt, clearly indicating the requested 10 CFR 35.300 authorizations, and including all required classroom and laboratory training, supervised work experience, clinical case studies, and preceptor attestations.

- c. The NRC Forms 313A (AUT) signed by Dr. Bradley and Dr. Butler indicate that Dr. Bhatt completed 4 cases each of 10 CFR 35.394, 10 CFR 35.396 (beta emitters & photon-emitting radionuclides with photon energies <150 keV), & 10 CFR 35.396 (other; photon-emitting radionuclides with photon energies > 150 keV) materials, during periods from September - December 2011, July 2007 - June 2011, & July 2007 - June 2011, respectively.

Please submit additional documentation supporting Dr. Bhatt's completion of at least 3 cases for each 10 CFR 35.300 category requested, per 10 CFR 35.390(b)(1)(ii)(G) requirements. For each case listed, include the date of administration, the radionuclide, the dose administered, the name of the supervising individual, and the radioactive materials license number on which the supervising individual is listed for the referenced use. For any person not listed on an NRC license, submit a copy of the agreement state license and/or permit authorizing the use at the time the case was completed.

2. As noted above, the NRC Form 313A (AUS) form, submitted in support of adding Dr. Bhatt as an Authorized User for 10 CFR 35.400 and 35.600 (limited to Iridium-192 in a high dose rate remote afterloader unit) materials, including 610 hours Classroom and Laboratory training, is inconsistent with the two submitted NRC Forms 313A (AUT). The February 2, 2011, request included a letter dated January 11, 2012, signed by Kristin Bradley, M.D., which provided
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a generic confirmation of Dr. Bhatt's total training and experience hours. The letter was unclear as to whether Dr. Bradley was confirming the 670 hours listed on the NRC Form 313A (AUT) forms, or the 610 hours listed on the NRC Form 313A (AUS).

As noted above, please provide additional documentation specifically outlining the number of hours of classroom and laboratory training completed, meeting the requirements listed in 10 CFR 35.390(b)(1)(i). The documentation should clearly explain any discrepancy between hours listed on the NRC Form 313A (AUT) and the NRC Form 313A (AUS).

3. The NRC Form 313A (AUS) indicates that Dr. Bhatt completed specific remote afterloader training and experience, as required under 10 CFR 35.690(c), from July 2007 – June 2011, under the supervision of Kristin Bradley, M.D. No additional details were included with the request to add Dr. Bhatt as an Authorized User for 10 CFR 35.600 (limited to Iridium-192 in a high dose rate remote afterloader unit) materials, as listed on the St. Luke's Hospital Radiology Department license, NRC License No. 24-01570-03.

Please submit additional documentation supporting Dr. Bhatt's completion of at least 3 treatments using iridium-192 in a high dose rate remote afterloader. For each case listed, include the make and model number for the high dose rate remote afterloader used, the treatment date, the name of the supervising individual, and the radioactive materials license number on which the supervising individual is listed for the referenced use. For any person not listed on an NRC license, submit a copy of the agreement state license and/or permit authorizing the use, including the specifically authorized make and model for the high dose rate remote afterloader at the time the case was completed.

In addition, if the listed clinical experience is for a different make and model HDR unit than the one authorized under the St. Luke's Hospital Radiology Department license, please indicate additional training completed or to be completed, specifically relevant to the HDR instrument listed on the St. Luke's Hospital Radiology Department license.

We have requested that you submit the referenced items:

- Classroom and Laboratory training details
- Single NRC Form 313A (AUT) as indicated
- 10 CFR 35.390(b)(1)(ii)(G) case details
- 10 CFR 35.690(c) case details
- Licenses &/or permits listing supervisors and/or preceptors, as needed
- St. Luke's-specific HDR make & model training information, as needed

– via facsimile, to (630) 515-1078. Please reference the Control No. 576920, as listed at the top of this memo. **Include a signed & dated cover letter with any additional information provided.** We expected to hear from you on or before May 2, 2012.

For future reference, please always include the name, phone number and fax number of at least one person whom we may contact for additional information when reviewing your licensing correspondence and requests.

Please submit the requested information within 14 days of this record. **Include reference control number 576920, Please FAX your response to my attention at (630) 515-1078.** You may also scan your response and send to me via email, as a pdf file.

Please direct any questions you have to me at **(630) 829-9892** or **sara.forster@nrc.gov**.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Sara A.B. Forster

Sara A.B. Forster 04/18/2012

Forster, Sara

From: Forster, Sara
Sent: Wednesday, April 18, 2012 3:07 PM
To: 'Durbin, Christopher M'
Subject: St. Lukes Hospital, Lic. No. 24-01570-03, C/N 576920
Attachments: 02240.57692.24-01570-03 telecon signed.PDF

Dear Dr. Durbin:

Please find attached a request for additional information, related to the request to add Dr. Bhatt as an Authorized User on the St. Luke's Hospital license, NRC License No. 24-01570-03. Please call me to discuss; also, if you have any questions. Please provide a response on or before May 2, 2012.

Sara A. B. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
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