



## CONVERSATION RECORD

August 7, 2014

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Edward Wroblewski, M.A.		DATE OF CONTACT 08/07/2014	TYPE OF CONVERSATION <input checked="" type="checkbox"/> E-MAIL <input type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING
E-MAIL ADDRESS eewroble@stvincent.org, RSO for		TELEPHONE NUMBER (317) 338-2381	
ORGANIZATION St. Vincent Hospital & Health Care Center	DOCKET NUMBER(S) 03001579		
LICENSE NUMBER(S) 13-00133-02	CONTROL NUMBER(S) 584189		
SUBJECT Second Request for Additional information needed to complete review of your amendment requests <i>Please address all elements/details requested completely.</i>			
SUMMARY We have reviewed your letters dated June 24, 2014, and July 18, 2014, and the unsigned (by your management, as the licensee) email response submitted on August 7, 2014 and find that we will need additional information as follows: Please note that, since your response -email was unsigned by your management and failed to contain the information we requested in our original request dated August 1, 2014, we could not consider it as an official response. All correspondence to us must be signed by a senior management official. We requested specifically that your response be signed as such and it contained no transmittal letter from you and no signature from a senior management official, etc. Please call me to discuss these matters to ensure an adequate response is forthcoming. 1. Paragraph three of your letter dated June 24, 2014, states, in part "Whilst I understand St. Vincent Hospital is not licensed for Gamma Stereotactic Radiosurgery & Teletherapy, my understanding is that Dr. Compton is eligible to be authorized for the latter two regulated materials & as such should be authorized."  <i>Continue on Page 2</i>			
ACTION REQUIRED (IF ANY) Please respond in writing within 20 days and address your response to my attention as "additional information to control number 584189." Your response must be legibly signed by a senior management representative, currently dated, and include a brief business letter of transmittal. If an alternative timeframe is needed to respond, please contact me by either telephone or email to make arrangements. My contact information is provided below. If you will need additional time to respond, we may partially issue those portions of your requests that are already acceptable. We would then defer conclusion of the remaining portion(s) of your requests until such time as you respond to our request for additional information in writing. We would then continue our review.  <i>Continue on Page 3</i>			
NAME OF PERSON DOCUMENTING CONVERSATION Colleen Carol Casey			
SIGNATURE <i>Colleen Carol Casey 8/7/2014</i>			

## CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

This statement is incorrect. Dr. Compton presents training and experience qualifications for modalities in 10 CFR 35.600 (i.e., gamma stereotactic radiosurgery and teletherapy) that exceed the only authorization in 10 CFR 35.600 that is authorized on this license (i.e., high dose rate remote afterloading brachytherapy). However, she cannot and should not be authorized for these modalities on this license at this time because the license does not authorize them, nor is a request for authorizing these modalities pending or undergoing current review with us.

We can only authorize persons on your license that correlate with the authorized materials and uses on your license. Therefore we are disregarding your request to authorize Dr. Compton for the gamma stereotactic radiosurgery and teletherapy modalities in 10 CFR 35.600.

2. Enclosure B to your letter dated June 24, 2014, contained Dr. Compton's application to become an Authorized User (AU) for materials in 10 CFR 35.400 and 35.600, limited to HDR brachytherapy, as noted above.

10 CFR 35.490(b)(3) and 10 CFR 35.690(b)(3) require proposed authorized users for these modalities to be physicians who:

Have obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1), or paragraphs (b)(1) and (b)(2), of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400; and, in Dr. Compton's case:

Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (a)(1) or paragraphs (b)(1) and (b)(2), and paragraph (c), of this section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

From NUREG 1556, Vol. 9, Rev. 2, Appendix D, Section V, "General Instructions and Guidance" for completion of Forms NRC 313a, second paragraph:

"To identify an individual (i.e., supervising individual or preceptor) who is authorized under a broad-scope license or broad-scope permit of a Master Materials License, provide a copy of the permit issued by the broad-scope licensee/permittee. Alternatively, provide a statement signed by the Radiation Safety Officer or chairperson of the Radiation Safety Committee similar to the following: "(name of supervising individual or preceptor) is authorized under (name of licensee/permittee) broad-scope license number to use (materials) during (time frame)."

Please refrain from submitting any information to us from IUPUI that pertains to the Gamma Knife and teletherapy programs as this information is extraneous for the current review.

In addition, the revised table submitted no longer shows Dr. Barriger's authorization on IUPUI at all, nor Dr. Compton's name so the table offers no useful information supporting Dr. Compton's application to become an AU. Please refrain from using it in response to this amendment again.

Also, IUPUI's RSO stated that Dr. Barriger was an AU, permit-holder for HDR and manual brachytherapy uses from 12/13/11 to 6/30/14. However, Dr. Compton's preceptor forms, signed by Dr. Barriger as supervising individual/preceptor state that Dr. Barriger supervised her training and experience from 7/1/10 - 6/30/14, which leaves a gap of about 17 months (7/1/10 - 12/13/11) when Dr. Barriger could not have supervised Dr. Compton as he was not an AU yet. Please explain and provide appropriately dated and signed preceptor forms accounting for the period of Dr. Compton's training and experience between 7/1/10 - 12/13/11. Please do not include training and experience or any information pertaining to modalities beyond manual brachytherapy and HDR.

CONVERSATION RECORD (continued)

ACTION REQUIRED (Continued from page 1)

Please note that the table submitted with Dr. Compton's preceptor forms does not provide the information requested in the guidance document. The table does not clearly identify the licensee, the license number, the date for which it is effective, the signature of the RSO or RSC chairperson and it is not inherently clear how this table supports Dr. Compton's application (and only Dr. Compton's application.) The license number should be included as well as the currently dated statement, currently signed by the Radiation Safety Officer or chairperson of the Radiation Safety Committee similar to the following:

"(name of supervising individual or preceptor) is authorized under (name of licensee/permittee) broad-scope license number to use (materials) during (time frame)."

3. We also noted that the signatures on each of your letters above were significantly different. One signature is quite large and the other is quite small, among other things. Please explain these differences and also, please note, that 10 CFR 35.12(a) requires that an application to us be signed by a licensee's management. Please have a senior manager sign your response to this request for additional information.

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>.

Colleen  
Colleen Carol Casey  
Materials Licensing Reviewer  
U.S. Nuclear Regulatory Commission  
Region III  
2443 Warrenville Road  
Suite 210  
Lisle, IL 60532-4352  
(630) 829-9841 Direct  
(630) 515-1078 Fax  
NRC 24 HR Operations Center  
(301) 816-5100

Gentle Reminders: Unless previously arranged with or requested by me directly, please do not submit any licensing requests, responses or correspondence via e-mail.

Please only submit one complete, signed copy of your correspondence to us.

Please prepare your licensing requests in accordance with NUREG 1556 Series Guidance, as appropriate.

Thank you very much!

Please also note that my full-time work schedule includes every other Friday off.

Ensuring the health and safety of  
our people, our nation and  
our environment

<http://www.nrc.gov/>

Repeat,  
from original  
Repeat  
from original