



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

August 17, 2020

Laura T. Speer Smith, M.S.
Radiation Safety Officer
Ascension Macomb Oakland Hospital,
Warren Campus
11800 E. Twelve Mile Rd.
Warren, MI 48093

Dear Ms. Smith:

This refers to the letter dated April 28, 2020 ("the letter") signed by you and received in our offices on May 26, 2020. This letter requests the addition of Rebecca Culcasi, M.S. as an authorized medical physicist (AMP) to your NRC license No. 21-01190-05.

We are unable to complete our review because the information in the letter is insufficient to support your request. Therefore, we are voiding your request until such time as you submit an appropriate written response as discussed below. "Void" simply means that we are taking your request out of our active casework database until we receive your response. Upon receiving your response, we will place it in our active database and continue our review.

If you wish to pursue this request, please provide only one response to the items below.

Please only send us one complete, written, currently dated and legibly, physically signed (by an appropriate senior management official) correspondence document, such as either an NRC Form 313 or a business-style letter containing the same information as an NRC Form 313a.

Please do not send multiple copies of responses and please do not submit any information that is identical to what you have already sent us unless we direct you to do so. If you resubmit such information for the sake of adding context and other details to enhance its meaning, that is acceptable.

Please do not email a PDF document to me, and transmit a faxed version, and/or a hard copy sent by mail. Only one copy transmitted in only one of these ways is appropriate to prevent administrative processing errors, although emailing a PDF document is the least efficient mechanism for responding to me.

The most reliable and fastest way to respond is to send a fax of one complete copy only to me at (630) 515-1078. In this circumstance, because we will need a copy of Ms. Culcasi's terminal degree documentation, sending your response by regular mail may be best.

Please address your written response to my attention as "additional information to control number 620010" to facilitate proper handling in our offices.

Please also schedule a telephone call with me and please include a senior management representative for this licensee to discuss the items in this letter. Arranging the call by email is preferable. My email address is colleen.casey@nrc.gov. My telephone number is (630) 829-9841.

A telephone discussion of these items may serve to clarify the information required by our regulations so that your response will be complete and accurate. We also want to ensure that the errors made in the letter and its attachments are not repeated in the future.

Please ensure that the requested information is answered completely and accurately.

Please be reminded that 10 CFR 30.9(a) requires: "(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."

1. Your letter states "Rebecca has completed a structured education program as noted under 35.690(b)(1) a 313A AMP form is attached."

This is incorrect. The regulations in 10 CFR 35.690 are for physician authorized users only. The correct regulations for Authorized Medical Physicists are in 10 CFR 35.51. In response, please simply acknowledge your understanding of this corrected information.

2. Your letter stated that you offered to scan in and email us a copy of Ms. Culcasi's degree but a copy of it was not provided in this letter, your original submission.

Please do prepare a complete and legible copy of Ms. Culcasi's terminal degree to demonstrate compliance with 10 CFR 35.51(b)(1). It is always best to provide us with complete documentation in the original request. Relying on us to ask for such documentation after the original request is received in our offices and processing is begun only serves to delay our review.

It may be best to submit this, and the rest of the response, via regular mail, since you stated that faxing a copy of diplomas does not result in a clear and readable version. Please do not send us your response separately from the copy of the diploma.

3. The NRC Form 313A (AMP) that was used for Ms. Culcasi appears to be a draft version because no Office of Management and Budget (OMB) clearance expiration date is shown on the form. NRC's Medical Licensing Toolkit website, in 2019, explicitly stated that these draft forms were not intended for use; they were intended for comment only.

The NRC Forms 313A have subsequently been released in Final Form, are on our Medical Licensing Toolkit website under "Forms" and have an OMB expiration date of 01/31/2023. These Forms became available in 01/2020, which appears on the Forms. Please use current and correct NRC Forms 313A for your response and for future requests.

4. 10 CFR 35.51(b) and (c) require, in part, that the authorized medical physicist be an individual who-

"(b)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

- (i) Performing sealed source leak tests and inventories;
- (ii) Performing decay corrections;
- (iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
- (iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (c) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51, § 35.57, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

(c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization."

The information submitted for Ms. Culcasi does not meet these requirements and it also fails to meet the requirements in 10 CFR 30.9, as stated above.

Specifically, the information submitted for Ms. Culcasi was signed by her preceptor on April 9, 2020, but her forms state that Ms. Culcasi was to have completed her additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization on May 29, 2020.

The letter transmitting your request was dated April 28, 2020, and it was received in our offices on May 26, 2020. These documents are inaccurate and incomplete in that they attest that Ms. Culcasi has completed required work experience by a

date beyond the dates specified in your letter and on her Forms. How could a preceptor attest to her completion of required work experience 50 days before she was scheduled to complete that work experience?

Please explain how and why these inaccuracies occurred and resubmit Ms. Culcasi's NRC Forms 313A AMP revised in their entirety, including appropriate preceptor signatures and dates.

Further, on page 5 of her Forms, the dates of Ms. Culcasi's education, training and experience for the Remote Afterloader is shown as "8/27/18 to present" for "Hands-on device operation," "Clinical use of the device," and "Treatment planning system operation."

The endpoint of her education, training and experience should be an actual date, month, day and year instead of "to the present," which is vague and non-specific. Please include these corrections to your revised Forms.

You may wish to refer to 10 CFR 30.32(b) and 30.32(c), as well as 10 CFR 30.33(a)(3) to assist you with your response. The guidance in "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report (NUREG-1556, Volume 9, Revision 3)", especially section 8.7.4 and Appendix D, may be useful in preparing your written response.

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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Colleen C. Casey

Digitally signed by Colleen C.

Casey

Date: 2020.08.17 15:12:05 -05'00'

Colleen Card Casey
Materials Licensing Branch

License No. 21-01190-05
Docket No. 030-02005
Control No. 620010