

From: [Forster, Sara](#)
To: [Ewald, Art](#)
Subject: Additional Information Request for Mount Clemens Regional Medical Center d/b/a McLaren Macomb amendment, NRC License No. 21-32190-01MD, CN 631950
Date: Thursday, September 08, 2022 5:55:00 AM

Good morning, Mr. Ewald:

Our office is in receipt of the July 20, 2022 letter requesting to add four authorized users to the referenced license, including Jacob Parzen, M.D., for 10 CFR 35.600 HDR use, and Sibin K. Zacharias for 10 CFR 35.200 use. Regarding Dr. Parzen's clinical HDR use experience, names of supervising authorized users and dates of supervised clinical HDR use were omitted. Regarding Dr. Zacharias's qualifications, documentation of recent training and experience was omitted. Accordingly, additional information regarding the addition of these two authorized users is needed to complete the review.

Regarding the information provided in support of adding a 10 CFR 35.600 authorization for Dr. Parzen, and for providing recent training and experience for Dr. Zacharias, please refer to NRC's NUREG 1556, Volume 9, revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," dated September 2019.

1. For Dr. Jacob Parzen, M.D., please provide at least three dates on which supervised clinical HDR treatments were completed. For each date listed, please also include the supervising AU, NRC or Agreement State License Number (or Broad Scope Licensee permit number), and manufacturer & model of the HDR used in the treatment. If more than three treatments were completed by the proposed AU, those may be submitted, but are not necessary. Please limit response to the proposed AU's experience and refrain from including sensitive information such as patient details.
2. For Dr. Sibin K. Zacharias, M.D., because the CBNC Board Certification included in the application is dated January 1, 2014, please provide additional recentness of training and experience completed within the past 7 years, relevant to the request to add him for 10 CFR 35.100 and 10 CFR 35.200 use. Please note that the training and experience may be continuing education, supervised clinical experience, or other relevant training. Please also note that there is no minimum number of hours required for this experience; only that it be sufficiently relevant and applicable and recent to meet the 10 CFR 35.59 recentness of training requirements.

NRC's medical licensing guidance, applicable HDR training regulation 10 CFR 35.690, and applicable recentness of experience regulation 10 CFR 35.59 may be found at the NRC's website, respectively, at <https://www.nrc.gov/docs/ML1308/ML13083A072.pdf>, <https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0690.html>, and <https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0059.html>.

Please provide a response via a signed and dated letter within 14 days (on or before September 22, 2022). If you are unable to provide a response before then, please provide a signed and dated letter by that date indicating the date by which you will be able to provide a written response to the items outlined in this request. Please note that substantial

delays in responding may result in a partial amendment to the license, adding Dr. Parzen for 10 CFR 35.400 use and the other two requested authorized users for 10 CFR 35.100 and 35.200 use. For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me by phone or email.

Sincerely yours,

Sara A. Forster, Health Physicist Licensing Reviewer

U.S. Nuclear Regulatory Commission - Region III

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From: [Sara Forster](#)
To: [Sandy Pavon](#); [Martha Pavon](#)
Cc: [Tammy Tomczak](#)
Subject: Request for Additional Information re Mount Clemens Regional Medical Center d/b/a McLaren Macomb Amendment Request, NRC License No. 21-04080-01, CN 631950
Date: Tuesday, September 20, 2022 12:47:41 PM
Attachments: [CN631950 RFAI email sent 20220908.pdf](#)

Good afternoon, Sandy & Martha:

Could you please place the attached document into ADAMS? It is a request for information to the referenced licensee, regarding the referenced mail control number.

Thank you!

Sara

Sara A. Forster, Health Physicist Licensing Reviewer

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