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March 23, 2021

Submitted via email to NRC Region IV: RidsRgn4MailCenter@nrc.gov
Submitted via certified mail to:

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555–0001

RE: Sanford USD Medical Center, NRC License #40-12378-01 (Docket No. 030-03249)
Dose in Excess of Regulatory Limit on Annual Exposure 10 CFR 20.2203(a)(2)(i)

To Whom it may Concern:

Sanford USD Medical Center (SMC) is submitting this report to the Nuclear Regulatory Commission (NRC) pursuant to 10 CFR 20.2203(a)(2)(i), regarding its discovery on February 22, 2021 that the uncorrected lens-of-eye dose for an Authorized User of Y-90 Microspheres exceeded 15 rem for Calendar Year (CY) 2020, as stated in 10 CFR 20.1201(a)(2)(i). This dose includes both contributions from handling Y-90 microspheres during procedures authorized under 10 CFR 35.1000 and from diagnostic range x-rays (both fluoroscopy and Computed Tomography). Details regarding this exposure are provided in Attachment 1 to this letter.

The dose to the Authorized User also has been found to be in excess of the quarterly ALARA limits for dose to the lens-of-the-eye under South Dakota Regulations. SMC submitted on December 11, 2020 a notification to SD-DOH (South Dakota Department of Health) for Calendar Quarter 2 of 2020, along with documentation of a proposed Eye Dose Reduction Factor for the leaded eyeglasses that the Authorized User wears. SMC is filing notifications with SD-DOH for Calendar Quarters 3 and 4 immediately before or concurrently with this report.

The Authorized User has received a personal copy of this report, as required by 10 CFR 20.2205. Please do not hesitate to contact me if you have any questions or comments. For technical questions, please contact Christopher Fischer, M.D., the Radiation Safety Officer, at 605-731-[redacted] (cell).

Sincerely,
Bridget O'Brien-Johnson

Bridget O'Brien-Johnson, MSN, RN, CNML
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NMSS

Attachments:
(1) Issue Details

(2) Personal Information of Affected Authorized User (Privacy Act Information Not for Public Disclosure)

Attachment 1: Issue Details

Date and Method of Discovery:

On February 22, 2021, SMC discovered that the lens-of-eye dose for the subject individual had exceeded 15 rem. The discovery was the result of a routine internal review of radiation exposure reports, including activities associated with the SMC annual NRC Form 5 report for 2020.

Background:

SMC routinely assigns two dosimeters to occupationally exposed individuals who work in interventional fluoroscopy and interventional CT rooms. This "double badging" practice covers Interventional Radiologists, Interventional Cardiologists, and certain surgical specialty physicians, such as Vascular Surgeons. Those staff who routinely work in suites with such "double badged" physicians are also provided with the same level of dosimetry coverage.

One of these "double badge" dosimeters is worn outside of all lead-equivalent protective gear at the collar level. The "raw" or uncorrected radiation exposures or doses are determined from this dosimeter. This includes the "raw" or uncorrected Lens-of-Eye Dose Equivalent (LDE) is reported by the dosimetry provider from the collar dosimeter. This also includes "raw" whole-body Skin Dose Equivalent (SDE) for the head and extremities.

The second dosimeter is worn on the chest underneath all lead protective garments. The readings for the two dosimeters are combined to form an Effective Dose Equivalent (EDE) exposure for the Deep Dose Equivalent (DDE) using the method described as "Provision 3" of Section 3.3.1 of NCRP (National Council on Radiation Protection and Measurements) Report 122 (published 1995, entitled "Use of Personal Monitors to Estimate Effective Dose Equivalent and Effective Dose to Workers for External Exposure to Low-LET Radiation"). The NCRP Report 122 EDE method selected allows the correction of the raw DDE to account for the dose reduction offered by wearing radiation protective gear during fluoroscopy procedures. The method for this calculation is approved by NVLAP (the National Voluntary Laboratory Accreditation Program of the U.S. National Institutes for Standards and Measurements). So, any NVLAP dosimetry provider can apply this EDE calculation to determine the worker's DDE from properly worn dosimeters.

This individual in this report is an Authorized User under 10 CFR 35.1000 for Y-90 microspheres. The Authorized User was assigned two sets of exterior dosimeters – one to record all radiation exposure and the second to record exposures only during the use of Y-90 microspheres (which may also include fluoroscopy to position or verify delivery of Y-90 microspheres). The exterior dosimeter that records all radiation exposures is used for the LDE and SDE (whole body) of the worker. The second set of exterior dosimeters, both collar and ring dosimeters (to determine beta doses to left and right hands) are worn only during Y-90 therapeutic procedures permits the licensee to evaluate SDE from such therapeutic procedures permitted by the NRC medical use license.

In this instance, the Authorized User wore leaded eyeglasses during fluoroscopy and CT procedures. The same glasses are worn during Y-90 microsphere procedures. SMC has been running an auditing program for leaded eyewear and proper dosimeter usage. This individual has not been found to either skip wearing leaded eyeglasses or their dosimeters. As the leaded eyeglasses are not covering the collar-

level exterior dosimeter, the protection effect of the leaded eyeglasses is not determined by the LDE reported by the NVLAP dosimetry provider.

From discussion of how to apply a correction to the LDE values with the Health Physicists at the NVLAP dosimetry provider, they are unable to apply any LDE corrections without a procedure approved by NVLAP. NVLAP has not approved any such procedure because the NCRP has not yet issued any report governing LDE corrections. The most recent NCRP Commentary in this area is Commentary Number 26 (issued 2016, entitled "Guidance on Radiation Dose Limits for the Lens of the Eye"). Section 7.2.2 of NCRP Commentary Number 26 does not provide a definitive approach to the calculation of corrected LDE when radiation protective devices are utilized and leaves this topic as a research issue for further investigation. Furthermore, the NCRP in this section of Commentary Number 26 called for the further refinement of the dosimetry methods of ICRP Publication 116 (International Commission on Radiological Protection, issued 2010, entitled "Conversion Coefficients for Radiological Protection Quantities for External Radiation Exposures"). The NCRP in Commentary Number 26 endorses the use of eye protection methods as discussed in NCRP Report 168 (issued 2010, entitled "Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures").

Analysis Methodology:

Without a definitive approach approved in an NCRP Report, NVLAP will not approve any method for applying correction factors to lens-of-eye doses. Even though leaded eyeglasses are consistently worn by the individual in this report, the NVLAP dosimetry provider cannot provide any automated calculations to reduce the reported and uncorrected LDE values. That makes SMC responsible for calculations of a corrected LDE with a Dose Reduction Factor (DRF) based on the actual devices used in medical procedures.

Neither the NCRP, nor the NRC have issued any guidance with any form of standardized method to allow a dose correction to account for using radiation protective eyewear. Therefore, SMC has developed a radiographic technique to verify the x-ray attenuation for prescription eyewear and leaded eyeglasses. Using this technique, SMC estimates that the leaded eyeglasses-reduced the x-ray exposure through the glass lenses was just over 1/32" lead-equivalent (0.79 mm lead-equivalent). Also note that because the leaded eyeglasses do not have side or bottom protection, SMC used an attenuation of 1/32" lead-equivalent to be conservative. With this attenuation, SMC also used a lens-of-eye Dose Reduction Factor (DRF-eye) of 2.0, which is toward the lower end of the DRF-eye value correction factors as reported by the NCRP in Section 5.5.4 of NCRP Report 168 (cited range is a dose reduction factor between 2 and 3 for leaded eyeglasses), as referenced in NCRP Commentary Number 26.

With a DRF-eye of 2.0, the corrected Authorized User's lens-of-eye dose for CY2020 is below the limit of 10 CFR 20.1201(a)(2)(i). Both the "raw" results from the NVLAP dosimetry provider and the DRF-corrected lens of eye dose are shown in the table included in Attachment 2. The dosimetry table in Attachment 2 also shows the results for both the radiation procedure dosimeter set, and the Y-90 therapy procedures dosimetry set. However, the results for the "Raw" Y-90 Microsphere Lens-of-Eye Dosimeter are incomplete as of the date of this report, as the December 2020 values are not yet available from the NVLAP dosimetry provider. We anticipate that the value will not significantly impact the corrected LDE results, as the Radiology dosimeter series was worn for all x-ray and Y-90 procedures. Due to COVID-19 conditions at SMC, the majority of the Y-90 procedures were conducted in October and December 2020.

Causal Discussion

There are three apparent causes for this report. First is the inability to directly measure the actual dose to the lens of the eye. Even the smallest microdot dosimeter worn inside of the leaded glasses causes impairment of the vision of, or a distraction to, an Interventional Physician. There are no possible corrective actions for this cause. The NCRP has not released an approved model for lens-of-eye dosimetry based on alternate dosimeter locations, such as eyeglass frame dosimeters or collar dosimeters.

Second is that the NVLAP dosimetry provider has no process to apply LDE correction factors. Such a process would require that the NCRP either issue an approved model for eye dose calculations from a collar dosimeter that is not close to the eyes, or would approve a process to implement lens-of-eye Dose Reduction Factors to take into account shielding of the eye that does not also shield the dosimeter used for eye dose assessment. Estimated LDE results based on a Dose Reduction Factor at the low end of the range listed in NCRP Report 168 is provided in the table of Attachment #2. The Licensee considers this to be a better estimate of the true dose to the lens of the eye than a dosimeter that is worn 10 to 14 inches away from the eyes.

The third apparent cause is that the NVLAP dosimetry provider does not provide a process to exchange the dosimeter designations for one month. This was combined with a user error in dosimeter placement, causing the collar and chest dosimeters were worn in exchanged locations. Instead of the requested exchange of location assignments with suitable documentation, the dosimetry provider used an addition and subtraction method which makes the EDE value for DDE come out correct but inflates the LDE and SDE values reported for that month. The corrected LDE results with an exchange of dosimeter readings is shown in the table in Attachment #2.

Corrective Actions Taken or Planned

The corrective actions taken and planned to ensure against a recurrence of the subject event are as follows:

In response to the first and second apparent causes:

(1) SMC will issue a dosimetry estimate and direct the NVLAP dosimetry provider to use that estimated value for the CY2020 LDE. The dosimetry estimate will take into account the dose reduction factor provided by the radiation protection devices (e.g., leaded eyeglasses) worn for the eyes. The estimated CY2020 annual eye dose for this individual that takes into account the use of leaded eyeglasses is shown in Attachment 2.

In response to the third apparent cause:

(2) Implement routine eye dose estimation for double-badged individuals who exceed 10% of the annual lens-of-eye dose limit. This dose estimation will occur within each calendar quarter to remain timely.

Additional correction action to prevent recurrence:

(3) Broaden the existing radio-protective eyewear auditing program to verify that double-badged individuals who exceed 10% of occupational radiation exposure limits to the lens of the eye consistently wear their eye protection.

Regarding these actions, SMC anticipates fully implementing corrective actions 1 and 2 by the end of quarter 2 of CY2021. Corrective action 3 is a long-term continuance of an existing program that was planned to be discontinued after a few quarters. That auditing program will now be permanent.