May 1, 2020

Submitted via email to jason.dykert@nrc.gov

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RE: Additional Information and Occupational Dose Calculations Requested During February 2020 Inspection at Sanford USD Medical Center (SMC) in Sioux Falls, South Dakota, NRC License #40-12378-01 (Docket #030-03249)

Dear Sir,

We attach a report of our continued work in response to your requests in the exit briefing and following your February 3 and 4, 2020 inspection of our facility. The issue of providing an occupational dose estimate related to the Interventional Radiology (IR) Authorized User (AU) for Y-90 microsphere therapies is addressed. We have not received any further communication from the equipment manufacturer since our February 11, 2020 letter about the issues pertaining to the instrumentation quality control of the Sr/Rb-82 generator flow-through calibrator.

We have conducted a review of Interventional Radiology (IR) physician occupational dose records and case workloads to determine the occupational dose per case. We also compared the occupational doses of the IR technologists and IR nurses who would be present in the room during IR procedures. We have de-identified the individuals for use in this executive summary letter. However, the individuals in IR are identified in the attached documentation. The attached reports show the input data, assumptions and calculations made to provide the information in this letter. From our analysis over the entire lifetime of the 10CFR35.1000 Y-90 microsphere authorization from the NRC, we have no IR physicians or staff who exceed the NRC or South Dakota Department of Health occupational dose limits for DDE, EDE or SDE. The Y-90 microsphere therapy program at SMC began in Calendar Year 2013 and continues to this day.

For the specific inspection request to estimate the occupational dose to the IR physician in the Y-90 microsphere program, we used the IR occupational records for 2017 through 2019. We have estimated the occupational dose for the IR physician and Y-90 microsphere Authorized User (AU) in question to not exceed 2300 millirem for DDE in Calendar Year (CY) 2019 from x-ray procedures. Over the life of the Y-90 microsphere therapy authorization, the program has not exceeded the calculated effective dose equivalent occupational dose limits for the AU when the radiation protective factor of a 0.5 millimeter lead-equivalent apron is included.

Although the occupational dose monitoring program for the AU in the Y-90 microsphere program is part of the questions during the inspection, we respond that we do have good, reliable dosimetry for the AU while in a Y-90 microsphere therapy procedure. This specific dosimeter was placed in a well-specified position on the exterior of the lead protective apron near the collar and was always worn during the Y-90 microsphere administration procedure and any fluoroscopy used to confirm delivery location and deliver condition. The Y-90 microsphere therapy procedures were designed with a "time out for Y-90 dosimeters" since the program inception in 2013. The case would not proceed if the three Y-90 dosimeters (external, near-the-neck whole body, left and right finger dosimeters) were not properly in place prior to final gowning and garbing of the IR staff. The Nuclear Medicine Technologists were trained to not turn over the Y-90 microsphere therapy dose if the therapy dosimeters were not in place. The Y-90 procedure dosimeters were always retrieved at the completion of the Y-90 microsphere therapy procedure and was not used for any other IR procedure. There was no such timeout in place for other IR procedures involving fluoroscopy for any IR physicians. Each staff member in IR was trained and considered responsible in the proper wearing of their occupational dosimeters.

As part of our corrective actions, we have reported our recommendations to the Radiation Safety Committee for SMC in Sioux Falls at the March 2020 meeting. This would include improved training and adding an analysis of unused and minimal dosimeter readings for physicians with fluoroscopy privileges for each department, with a referral to the RSO and radiation safety to investigate repeated findings. This will be handled as part of the ALARA investigation and reporting process. The SMC RSO also reports that [redacted] is in full support of the changes in the program and will be fully compliant with our recommendations for improved monitoring of occupational dose moving forward.

We look forward to providing any additional information to respond to your questions in a timely manner. Please do not hesitate to contact me if you have any questions or comments. For technical questions, please contact Dr. Chris Fischer, Radiation Safety Officer at [redacted] (cell) or Jennifer Stapleton, Associate Radiation Safety Officer at [redacted] (cell).

Sincerely,

Kelly Hefti

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Report of Interventional Radiology (IR) Occupational Dose Analysis

Sanford USD Medical Center (SMC) in Sioux Falls, SD

April 2, 2020 with revisions of April 30, 2020 through May 8, 2020

Prepared by: Richard J. Massoth, Ph.D.

Background

In Calendar Year (CY) 2013, Sanford USD Medical Center in Sioux Falls, SD (hereafter SMC) applied to the U.S. Nuclear Regulatory Commission (NRC) for a license amendment to permit Y-90 microsphere therapies with both SIRsphere and TheraSphere devices that are included in 10CFR35.1000 uses. There was a newly hired Interventional Radiology (IR) Physician who was joining SMC from an IR Fellowship at the University of Kansas Medical Center (KUMC) in Kansas City, KS. KUMC has a Medical Broadscope License from the State of Kansas and trains their IR Fellows in Y-90 microsphere therapy procedures.

When this Y-90 microsphere license amendment was requested by SMC from the NRC, there were two IR Physicians already in practice at SMC who sought a new IR Physician Partner. The occupational dosimetry and Radiation Safety Officer for the physician practice, including IR was held by Sanford Clinic Radiology, which is a clinic-based medical specialty practice group. This is a corporate entity separate from SMC under the corporate umbrella of Sanford Health. The IR Physician occupational badges were managed by RT staff from Sanford Clinic Radiology. The RSO for x-ray exposures within Sanford Clinic Radiology was named from among the Radiology Physicians for Sanford Clinic Radiology (SCR). This was a different RSO reviewing x-ray occupational doses for physicians as compared to the RSO for SMC. The signatures of the reviewing SCR RSO and often the reviewing RT dosimetry manager will appear at the bottom of dosimetry pages addressed to SCR. The dosimetry results of the SCR program are (at least since 2013) also reported up to the SMC RSC.

At the same time as the Y-90 microsphere license amendment was requested by SMC from the NRC, there was a separate NRC License for Sanford Clinic Nuclear Medicine. Sanford Clinic Nuclear Medicine was also a separate corporate entity from SMC, and had a different RSO for Radioactive Materials Use in Medicine that was separate from the SMC Radioactive Materials License. The Sanford Clinic Nuclear Medicine program has been subsequently Decommissioned by their staff and that license was Terminated by the NRC several years ago.

At the time when the Y-90 microsphere license amendment was requested by SMC from the NRC, all Radioactive Materials Use within Sanford Hospital and Cancer Center was covered under the SMC License from NRC. The management elected to put forward the Y-90 microsphere therapy authorization under the SMC license instead of under the separate Sanford Clinic Nuclear Medicine license. The RSO in CY2013 and CY2014 for Sanford Clinic Nuclear Medicine and SMC was the same individual, and was an Authorized User (AU) on both Radioactive Materials Licenses. The medical physicist for both institutions at the time was also the same individual, who is listed as an Authorized Medical Physicist (AMP) on the NRC license for SMC.

The newly hired IR Radiologist began practice at SMC, while working for Sanford Clinic Radiology (SCR). The occupational dosimetry for SCR was ordered as if for a non-IR Radiologist, which was a single dosimeter to be worn on the outside of any lead protective apron. At the time, the other IR Physicians had been assigned two dosimeters, with one to be worn on the outside of their lead aprons and the other to be worn under their lead apron(s) near their waist. No IR or other Radiology Physician occupational dosimeters were provided by SMC, only SCR.

When the newly hired IR Radiologist began the Y-90 microsphere program, as soon as NRC authorized 10CFR35.1000 use for Y-90 microspheres on the SMC Radioactive Materials License, additional occupational dosimeters (a Whole Body and extremity dosimeters for left and right hands) were ordered for use during Y-90 microsphere procedures. This was done in order to differentiate between occupational exposures during Y-90 microsphere therapies and "routine" IR fluoroscopy exposures. The Effective Dose Equivalent exposures were to be always combined by the NVLAP-accredited dosimetry provider for both SCR and SMC. However, they were not always combined in the same manner or with the same methodology as intended. To further complicate the occupational dosimetry of the early Y-90 procedures, the training and early cases may not have been captured on the specific SMC Y-90 therapy occupational dosimeters for the IR Authorized User until the last quarter of CY2013. By the fourth quarter of CY2013, the Y-90 microsphere specific occupational doses have been faithfully captured independently of the IR occupational dosimeters.

The single dosimeter occupational doses reported by the NVLAP-accredited supplier were <u>not</u> corrected for lead apron usage in CY2013 and the results were not comparable to the EDE values for the other IR Physicians. This alarmed the SCR RSO, who began an ALARA investigation of the new IR Physician's use of x-ray radiation and recommended a review of Radioactive Materials exposures of the same IR Physician. The RSO for SMC requested an analysis from medical physics, who provided an analysis. The analysis showed that there was a difference between the dosimetry orders for the IR Radiologists by SCL and that there was no correction being applied to credit consistent use of lead aprons as a radiation protection method. Effective Dose Equivalent (EDE) Calculations were provided to SCR, but these results were not requested to have the NVLAP-accredited dosimetry provider provide a corrected EDE for deep dose exposures. Calculated EDE values for the IR Radiologist who was also listed as an SMC AU for Y-90 microsphere therapies were not applied by the NVLAP-accredited dosimetry provider. There are contemporaneous records of RSO reviews of dosimetry and the medical physics calculations of EDE for the IR Radiologist AU are on file at SMC for review by the NRC.

Subsequent to this particular ALARA investigation, the SCR staff corrected the dosimetry order for the IR Radiologist AU. Dosimetry for the IR Physicians has been more consistent with the double-badging recommendations of NRCP Report 122 since that time.

With an organizational restructuring in the early 2010s, SMC started having the SCR occupational dosimetry results reported to the SMC Radiation Safety Committee for a consistent ALARA program. This change brings the SMC RSO into the review of occupational doses for the uses of x-ray radiation across the SMC campus in Sioux Falls. The established practice became to report occupational dose ranges by department with results of ALARA investigations reported to the Radiation Safety Committee (RSC) and the SMC RSO. Some of the departments did perform a review of unused and minimal occupational exposures, but not every department. This left an unintended weakness in the occupational dose monitoring program at SMC. This was the condition found during the February 2020

NRC inspection of SMC. To correct the weakness, it is necessary to have each department investigate unused and minimal exposure dosimeters as part of the ALARA program and report the results to the RSO and the RSC for SMC in Sioux Falls. This was discussed with the SMC RSC at the March 2020 meeting as part of the corrective action plan following the February 2020 NRC inspection.

Methods of Procedure

A study of IR Physician workload was conducted. For this study each of the three IR Physician Peer Procedures were evaluated. An attempt to classify the different procedures was made. The data (attached detail) show the results of this study. Overall, the IR workload in x-ray procedures appears fairly balanced. As a result, the highest IR Physician EDE values should be able to be used for the upper bound of the EDE estimates when actual as-worn dosimetry is unavailable or unreliable. Corrections will be needed to account for the fact that there is no Y-90 microsphere exposure to the IR Radiologists other than a Y-90 microsphere AU. An analysis of reliability of IR Radiology occupational doses will also be needed to evaluate the validity of the high occupational dose estimates. These estimates are presented in the results section.

A comparison study of IR staff occupational doses was performed to provide a second comparison and "sanity check" for the IR Physician peer occupational dose estimate. There were two comparison groups: IR radiologic technologists (RT) and Radiology Nurses (RN). It is necessary to consider their closeness to the radiation sources in the room with respect to Y-90 microspheres during therapies and x-ray during all other IR procedures. This should allow their occupational dose readings to serve as an extreme lower bound on the IR Physician occupational doses.

In the IR procedures, the RN performs patient monitoring and medication support duties. The RN is farther from the x-ray beam or any Y-90 microsphere therapy use than are the IR Physicians or IR RT staff. The RN staff are present for IR cases where needed, and have a different rotation schedule than the IR physicians. The RT staff are "scrubbed in" and at the elbow of the IR Physician, but are farther from the x-ray source by approximately one meter. Their occupational doses are expected to be a better estimate for the lower bound of IR Radiologist exposures than the RN staff. The RT staff will be closer to the x-ray beam and have a very different rotation schedule than either the RN or IR Physician staff.

It is also possible to model the location of the RT during IR cases. NCRP Report-168 considers the IR Physician to be located 0.75 meters from the average center of the fluoroscopy x-ray source. Assuming that the IR RT is located within 1 meter of the IR Physician when "scrubbed in" for the case, it should be possible to perform a distance correction to the IR RT dosimetry data as an alternative estimate of IR Physician dosimetry values. Based on observations, the IR RT and IR RN staff are much more consistently wearing their occupational dosimeters. In the interest of brevity, results of this dose estimation method are not shown.

A literature search for Interventional Physician occupational doses on a per-case basis was conducted. A primary source for these values is contained in NCRP Report 168, released in 2013, with Dr. Balter as chair as well as Dr. Miller and Dr. Schueler as co-vice-chairs of the document group. However, there are some more recent literature reports from which outside-of-the-apron procedure doses can be compared to the IR Physician dosimeters. These reported values of maximum occupational dosimeter readings and calculated Effective Dose values are included in the results table in the section below for comparison with SMC-specific occupational dose estimates.

The available dosimetry records from the NVLAP dosimetry suppliers were reviewed and summarized. These values were used for calculations of occupational dose to the IR physicians. These results appear in the tables of the Results section.

Results

The results of the procedure count and type analyses between the IR Physicians for the CY2013-2019 range are presented in Table 1. The procedure count and types were found to be approximately the same for each IR Physician, with variation more likely driven by the patients who present for IR procedures during the regular IR rotation of the IR Physicians. The only exception is for Y-90 microsphere therapies, for which there is only one IR Physician who is an AU on the SMC license. The other IR Physicians are not performing Y-90 microsphere therapies.

Table 1: IR Procedure Count Comparison for IR Physicians (without Y-90 microsphere procedures)

Calendar Year	*Y-90 Microsphere AU*	*IR Partner 1*	*IR Partner 2*
2019	1380	1117	1380
2018	1060	1093	1349
2017	1050	921	1385
2016	1200	1016	1366
2015	1128	843	1429
2014	940	788	1305
2013	859	947	1122

Table 1 Notes: (1) IR Partners 1&2 have been with SMC for over 10 years. The Y-90 microsphere program started part-way through CY2013 when a new IR Partner was added as a Y-90 AU under 10CFR35.1000. Y-90 microsphere procedure volume ranges between 12 and 42 over this span of years. (2) Only traditional fluoroscopy and CT interventions are included in the data in Table 1. Y-90 microsphere therapy cases are considered separately.

Shown in Table 2 is the calculated dose per IR procedure for each of the three IR physicians, where the outside-the-apron dosimeter is used. The maximum dosimeter value for the x-ray dosimeters is used for this calculation, as that should be the “true” outside-the-apron dosimeter, and cannot be confused by the labeling of the dosimeter by the user or the NVLAP dosimetry provider. The Y-90 AU doses are separated by the use of the two different external dosimeters. The dosimeter that is worn at the collar during Y-90 therapy phase procedures may receive both x-ray and Y-90 beta and bremsstrahlung exposures. It is referred to as the “Y-90 Therapy Phase Dosimeter” and is positioned by the Nuclear Medicine Technologist who delivers the Y-90 microsphere therapy dose to the AU in the IR procedure room. This Y-90 Therapy Phase Dosimeter will record the beta dose during Y-90 microsphere therapies, but may also receive x-ray fluoroscopy doses during verification of delivery of the Y-90 microspheres.

Table 2: Occupational Dose Results Per IR Procedure for "Mixed IR Procedures" – Peak (outside the apron) External Dosimeter ONLY (without any NCRP Report-122 corrections for lead apron shielding)

Calendar Year	***Y-90 Microsphere AU Estimated X-ray Only (millirem per IRcase)***	***Y-90 Microsphere AU Estimated Y-90 Therapy Phase Only (millirem per IRcase)***	***IR Partner 1 (millirem/IRcase)***	***IR Partner 2 (millirem/IRcase)***	***NCRP Report-168 Table 5.1 Values for Peak Dosimeter Value (millirem/IRcase)***
2019	1.1 (estimate)	2.1	2.3	0.56 (questionable)	5 to 32.5
2018	1.1 (estimate)	2.2	1.1 (estimate)	1.09	5 to 32.5
2017	1.0 (estimate)	2.9	1.0 (estimate)	1.01	5 to 32.5
2016	1.6 (estimate)	1.4	1.6 (estimate)	1.56	5 to 32.5
2015	0.48	2.56	0.2	1.34	5 to 32.5
2014	2.16	3.1	0.7	3.02	5 to 32.5
2013	6.51	4.4	0.5	0.76 (questionable)	5 to 32.5

Table 2 Notes: (1) Y-90 microsphere therapy phase dosimetry data from the "time out" Y-90 therapy dosimeters used at SMC for evaluation of beta exposure during 10CFR35.1000 microsphere delivery. (2) NCRP Report-168 peak dosimeter values are from published literature for a limited number of facilities and do not represent national or international ranges. (3) Items marked "questionable" represent where a significant number of dosimeters appear to have been interchanged during the year. As a maximum dosimeter value was used as the external dosimeter for this analysis, even if that dosimeter was marked as being "under apron". (4) Items marked as "estimate" are estimated from the dose/procedure of an IR peer at SMC when very low, "M" or zero values were reported from occupational dosimetry.

Shown in Table 3 are the results of determining the EDE to the IR Physician for each IR case. The emphasis is on converting the reported DDE for one or two dosimeters into an occupational dose per IR fluoroscopy or CT procedure. Wherever possible the EDE1 value is presented. When data from only one external to the apron is available, then EDE2 (based on one of Webster's formulae) is provided. The South Dakota Department of Health prefers that EDE1 be used for occupational dosimetry, and distrusts the use of Webster formulae for occupational dosimetry in medicine when lead aprons are routinely used. All of the calculational methodology is based on NCRP Report-122, and is used by the NVLAP-accredited dosimetry providers. If the dosimetry reports do not perform the EDE calculations directly, then it is necessary for the Health Physicist to manually calculate the EDE from the raw, uncorrected dosimeter readings.

Table 3: Occupational Dose Results Per IR Procedure for "Mixed IR Procedures" – External Effective Dose Equivalent (EDE) per IR Procedure with Corrections to Include Radiation Protection Factor for Lead-equivalent Apron Use (NCRP Report-122 corrections for wearing a lead apron)

Calendar Year	***Y-90 Microsphere AU x-ray ONLY (millirem/IRcase)***	***IR Partner 1 (millirem/IRcase)***	***IR Partner 2 (millirem/IRcase)***	***NCRP Report-168 Table 5.1 Values (millirem/IRcase)***
2019	1.1 (estimate)	1.6	0.48	0.17 to 1.5
2018	1.1 (estimate)	1.1 (estimate)	1.02	0.17 to 1.5
2017	1.2 (estimate)	1.2 (estimate)	1.16	0.17 to 1.5
2016	1.4 (estimate)	1.4 (estimate)	1.38	0.17 to 1.5
2015	0.09 (unreliable)	0.22	0.38	0.17 to 1.5
2014	0.4	0.73	0.31	0.17 to 1.5
2013	1.16	1.1 (estimate)	1.14	0.17 to 1.5

Table 3 Notes: (1) IR Partner 1 wears a frontal-only lead apron instead of a wrap-around. This is to save weight and reduce back pain during IR procedures. Under-apron dosimeter placement affects measured results. (2) Items marked "estimates" are taken from IR partner data for which good occupational dosimetry is found, and the only corrections needed were to identify when the outside and inside dosimeters had been obviously exchanged.

Shown in Table 4 are the reported dosimeter values with EDE1 and EDE2 calculations applied for each year since the inception of the Y-90 microsphere program at SMC. The values are shown only for the Y-90 microsphere AU on the SMC license from NRC. These values will be used to generate Table 5, which presents the occupational dose per IR procedure for the Y-90 AU physician for the lifetime of the Y-90 microsphere program at SMC.

Table 4: Occupational Dose-Corrected EDE determinations (Corrected with NCRP Report 122 Radiation Protection Factors for Lead-Equivalent Apron Use) for the Y-90 Microsphere AU – IR-only Dosimeters (which would also include Y-90 microsphere therapy doses if worn correctly)

Calendar Year	***EDE1 Calculation (millirem)***	***EDE2 Calculation (millirem)***	***NVLAP Dosimetry Provider***	***Includes Y-90 Therapy Dosimeters***	***Notes***
2019	0	0	Mirion	No	Correction to match IR Partner dosimeter range needed, as so many dosimeters returned unrealistically low values. No Y-90 therapy badge data included, which do show a dose.
2018	98	25.5	Mirion	No	Correction to match IR Partner dosimeter range needed, as so many dosimeters returned unrealistically low values.
2017	7	18	Mirion	No	Correction to match IR Partner dosimeter range needed, as so many dosimeters returned unrealistically low values.

Calendar Year	EDE1 Calculation (millirem)	EDE2 Calculation (millirem)	NVLAP Dosimetry Provider	Includes Y-90 Therapy Dosimeters	Notes
2016	6	26.8	Landauer	No	Maximum dosimeter DDE was reported as estimated dose. Few returned IR dosimeters.
2015	593	97.5	Landauer	No	Maximum dosimeter DDE was reported as estimated dose.
2014	306	362	Landauer	No	Maximum dosimeter DDE was reported as estimated dose.
2013	234	998	Landauer	No	Two dosimeter method began in September 2013. Maximum dosimeter DDE was reported as estimated dose.

Table 4 Notes: (1) Webster calculation of EDE2=DDE/5.6 used, but on occasion some contemporaneous notes used 0.3*DDE, which is an alternative Webster calculation. (2) EDE1 calculation based on 0.04*outerDDE+1.5*underDDE, but on occasion some contemporaneous notes used 0.03*outerDDE+1.5*underDDE for under-apron versus outside-of-apron EDE1 calculations. (3) EDE1 calculations can only be used when two dosimeters are used. It is necessary with EDE1 to consider whether the two dosimeters have been confused or exchanged by either the wearer (if they mount their own dosimeters), by the individual mounting the dosimeters, or by the location designations used by the NVLAP dosimetry provider. (4) The highest dosimeter reading is used as the outerDDE value in this report.

Table 5: Occupational Dose-Corrected EDE determinations (Corrected with NCRP Report 122 Radiation Protection Factors for Lead-Equivalent Apron Use) for the Y-90 Microsphere AU – IR-only Dosimeters

Calendar Year	IR Procedure Count	Y-90 µsphere Therapy Phase Count	EDE1 per IR Procedure (millirem)	EDE2 per IR Procedure (millirem)	Estimated Occupational DDE (EDE1) with apron protection factor (millirem)	Notes
2019	1380	12	1.1	0.2	1518	EDE1 and EDE2 are based on most reliable IR Partner dose per procedure, based on missing or unreasonably low dosimetry values.
2018	1060	16	1.1	0.2	1166	Same note as CY2019.
2017	1050	16	1.0	0.2	1050	Same note as CY2019.
2016	1200	33	1.6	0.3	1920	Same note as CY2019.

Calendar Year	***IR Procedure Count***	***Y-90 μsphere Therapy Phase Count***	***EDE1 per IR Procedure (millirem)***	***EDE2 per IR Procedure (millirem)***	***Estimated Occupational DDE (EDE1) with apron protection factor (millirem)***	***Notes***
2015	1128	36	1.3	0.3	1466	EDE1 & EDE2 is based on most reliable on IR Partner dose per procedure when dosimetry was considered unreliable.
2014	940	42	2.2	0.3	2068	Training effect still noted. Dose per case for 2014 also used for 2013.
2013	859	12	2.2	0.3	1899	Partial year of 8 months. Dosimetry changed twice during year. AU straight from IR fellowship. Training effect is anticipated.

Table 5 Note: Estimated Occupational DDE with correction for the Radiation Protection Factor of the lead apron is based on comparison with IR Partners where dosimetry is missing, or dosimeters were not turned in for processing. Training effect is expected and observed.

Table 5 shows the results for SMC IR physician who is an AU for Y-90 microspheres. The practice volumes shown in Table 1 demonstrate that the workload in x-ray based IR procedures is roughly the same for each of the IR physicians. NCRP Report 168, Table 5.1, shows that a per-case corrected DDE of 0.17 to 1.5 millirem, with a peak dosimeter reading in the range of 5 to 32.5 millirem per case. From the tables above, for the SMC IR physicians, the per-case corrected DDE from EDE1 calculations is 0.38 to 1.38, toward the low end of the NCRP Report 168 range._ However, even doubling the measured and estimated occupational dosimetry from Table 5 as a "safety factor" above the reported values remains below the NRC regulatory limit of 5000 millirem (DDE) from 10CFR20.1201.

Discussion

The occupational Effective Dose Equivalent (EDE) results for these physicians may be used to determine the missing or reported as "minimal" occupational EDE for the Y-90 microsphere AU in cases other than Y-90 microsphere therapies. The Y-90 microsphere therapy EDE values should be added to the estimated EDE values (for DDE, LDE and SDE) when the non-microsphere fluoroscopy EDE is zero to account for the additional Y-90 microsphere case workload. This was presented in the results section.

Two estimates of the occupational dose for the Y-90 microsphere AU Physician in IR are provided in the results section of this report. The first is the highest dose estimate from the IR Physician Peer group. This is based on the occupational dose per IR procedure value calculated from reliable occupational dosimetry records. The second estimate is based on literature values from NCRP Report 168 or studies published in peer-reviewed literature from the Society for Interventional Radiography (SIR) or a Medical Physics or Health Physics peer-reviewed journal.

Based on the literature reviews of Y-90 external exposures (see Alhazmi's M.S. Dissertation), the external exposure to Y-90 therapeutic agents is attenuated by a lead apron as used in IR procedures. The additional occupational dose from Y-90 beta radiation and bremsstrahlung will contribute to external exposure to the skin of the extremities, the lens of the eye and the skin of the head. It was for this purpose that Y-90 procedure dosimeters were ordered and used. In this instance, the dosimeters can also provide a per-procedure estimate of external dose to the IR Physician. The Y-90 procedure dosimeters are exposed to the Y-90 beta radiation, bremsstrahlung and any fluoroscopy used in the administration phase of the Y-90 microspheres. As the ring dosimeters in Y-90 therapy procedures are underneath at least one layer of surgical glove, then may experience more attenuation of the beta dose component relative to the external beta dosimeter at the collar of the IR Physician.

In future work, it should also be possible to estimate the low end of the Y-90 microsphere AU physician occupational dose from a distance corrected RT staff occupational dose in IR. The assumption would be that the RT staff is one meter farther from the radiation source during x-ray procedures. NCRP Report 168 assumes that an IR Radiologist stands 0.75 meters from the x-ray tube during fluoroscopy, so with the proper geometric correction, a third method of estimating IR Physician doses from the "scrubbed in" IR technologist staff could be provided. It is not considered likely by the authors that this will increase the estimated EDE dose per case in x-ray procedures.

Conclusion

The Occupational Effective Dose Equivalent (EDE) for the IR Physicians at SMC (or SCR) is below the Occupational Dose Limit for South Dakota Department of Health Regulations when corrected for use of lead aprons. The EDE values are also below the regulatory notification and reporting levels even when not corrected. This holds over the entire study period when Y-90 microsphere therapies have been authorized by the NRC for SMC.

The estimated range of EDE values per procedure for IR Physicians at SMC in Sioux Falls, SD during CY2019 is 0.5 to 1.6 millirem per procedure, when a radiation protection factor provided by wearing lead aprons is included. This is in reasonable agreement (within 6.7%) from Table 5.1 of NCRP-168 of 1.7 to 15 microSieverts per procedure (0.17 to 1.5 millirem per procedure) for mixed IR procedures. This permits an estimation of the occupational EDE for the Y-90 microsphere IR AU in CY2019 to be 1518 millirem. The peak occupational dosimeter value, if the dosimeters had been worn correctly would have been reported as 3174 millirem for CY2019.

SMC will await the NRC response to this report before making further changes in the ALARA program beyond the corrective actions already undertaken.

References/Footnotes

(1) NCRP Report 122. Entitled: "USE OF PERSONAL MONITORST TO ESTIMATE EFFECTIVE DOSE EQUIVALENT AND EFFECTIVE DOSE TO WORKERS FOR EXTERNAL EXPOSURE TO LOW-LET RADIATION" NCRP, December 1995. National Council on Radiation Protection and Measurements (NCRP). Bethesda, MD.

(2) NCRP Report 168. Entitled: "Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures", NCRP, July 2010. National Council on Radiation Protection and Measurements (NCRP). Bethesda, MD. Report chair was Dr. Steven Balter with vice-chairs of Dr. Beth Schueler and Dr. Donald Miller.

(3) NRC Regulations 10CFR Parts 19 and 20. Most importantly 10CFR20.1201, 10CFR20.2203 and 10CFR20.2205.

(4) NRC Regulatory Guidance Review (which may or may not be in force):

(a) U.S. NRC Regulatory Guide 08-018, Revision 1. October 1982.

(b) U.S. NRC Regulatory Guide 08-029, Revision 1. February 1996.

(5) L. Vergoossen, et al., Med Phys **43**(6): 3669-3669 (2016). Abstract cites an occupational EDE 84.7 microSieverts per procedure for abdominal interventions with a variance of 106 microSieverts per procedure. In US traditional units, 8.47 millirem per case with a variance of 10.6 millirem.

(6) Master's Dissertation/Thesis on External Exposures from Radioactive Materials, including Y-90. Entitled: "Review of lead aprons efficiency for radionuclides used in the Grove Centre" by Abdulaziz Alhazmi, University of Surrey (UK), Department of Physics, September 2011. Released through IOMP (International Organization of Medical Physicists).