Radiation Advisory Committee Meeting Minutes
October 12, 2022

Attending Advisory Members
David Hamby – Oregon State University
Dennis Wood – Medical Physicist
Mandy Henrikson – Operating Partner for Palm Beach Tanning
Bob Berry – Providence Portland – Radiation Safety Officer
Jennifer Frankel – Dentist in Keizer
Juliana Cyman – Veterinary Radiation Oncologist
Betty Brown – Portland Open Bible Community Pantry

RPS Staff
Todd Carpenter
David Howe
Hillary Haskins
Brent Herring
Alex Parker
Toby Irving
Daryl Leon
Rich Patterson
Tom Pfahler
Judy Smith
Patty Thompson
Ram Wusirika

Guests
Alicia Zambelli - Veterinarian
Garrett Frey – RSO & Safety Manager for Knife River Corp Northwest
Robin Holm – OHA-HSPR – Regional Emergency Coordinator for Region 1
Laurie Sanders – Samaritan Health
Devin
Luke
Megan Norman
Will Sharon – OXOS Medical Inc.
Dev Mandavia – OXOS Medical Inc.
Evan Ruff – OXOS Medical Inc.
Susan Atkinson – OXOS Medical Inc., legal counsel

June RAC Meeting Minutes approval- RAC Chairperson Barb Smith
Motion by Bob Berry
Second by David Hamby
Meeting minutes approved

RPS Staffing- RPS Program Director David Howe
Introduction of Rich Patterson – New Environmental Health Specialist (EHS3)
Introduction of Sarah Brodesser – New EHS3- RPS now has a fully authorized 18 member staff

To rebalance managerial ratios, the RPS Program Director moved three team members from Hillary Haskins supervision to Todd Carpenter. The staff moved to Todd Carpenter are field staff (Daryl Leon, Tom Mynes, Tom Pfahler) who also have RML responsibilities.

Moment of silence for RAC Member Scott Young

RAC member nominees- David Howe
Two nominees for RAC membership were introduced, as candidates for appointment by the OHA Director, including Veterinarian Alicia Zambelli and Industrial RS0/Safety Manager Garrett Frey.
Barb Smith moved to nominate both candidates, Many Henrikson seconded.
Passed unanimously by the RAC members

Nomination of RAC Chair and Vice Chair
RAC Member Mandy Henrikson nominated Barb Smith for re-appointment to a second, two-year term as RAC Chairperson. Seconded by Bob Berry – approved unanimously by the RAC committee.

Barb Smith nominated Bob Berry to be the RAC Vice Chair for a two-year term. Seconded by Mandy Henrikson- approved unanimously by committee

RPS Program Updates

Fiscal Year 2021-2023 transition to New State Financial System Financial Reports delayed - no new numbers to report
Mammography Quality Standards Act (MQSA) 5-year contract has been renewed

Electronic/Tanning Inspection Update by Brent Herring

New inspectors

- Toby Irving: Signed off to perform independent dental, veterinary, chiropractic, medical and MQSA inspections
- Dong Lim: Signed off to perform independent dental and tanning inspections
- Rich Patterson: Signed off to perform independent dental inspections

Inspections performed since last Radiation Advisory Committee meeting
159 x-ray inspections (medical, dental, veterinary, therapy and industrial)
21 MQSA
25 tanning

RML Program update (y-t-d) by Hillary Haskins
63 inspections completed
37 left for the year
136 licensing actions completed

99 open licensing actions

Emergency Response/Incident Reports by Hillary Haskins
Incident

- Notice of Violation issued to OHSU Tuality for Physician overexposure for occupational radiation dose of 25 Rem per year.
- Notice of Violation issued to SkinCure Oncology & Central Oregon Dermatology for seven superficial brachytherapy fractions to the wrong site on patient

RPS Training- Hillary Haskins
NRC training attended by staff include courses for IMPEP evaluator course, Inspection procedures, Security, Environmental sampling, Nuclear Medicine and Gamma Knife and High Dose Rate (HDR) Afterloader.

Upcoming training

- RPS will be helping to train Washington Department of Health Radiation Protection Inspectors to perform facility inspections based on our current practices as a guideline for their program

Exemptions/Rules/Statutes

OXOS Medical Inc. – Follow up on Micro C Medical Imaging System M01

OXOS did a follow up presentation (from the June RAC Meeting) to address RPS-RAC Member questions.

OXOS representatives shared that the Micro C M01 System has FDA clearance for pediatric populations and surgical populations. The Micro C M01 is a complete system with the X-ray source and detector being physically tethered together. The emitter, the control unit, and the cassettes are all integrated. The emitter houses the X-ray source, and the cassette houses the flat panel detector.

The machine has a unique safety and positioning system. The X-ray emitter that houses the X-ray source, and the cassette that houses the flat panel detector, "know" where each other are in space, and they prevent any X-ray emission unless they are positioned orthogonal to one another within the proper SID and SSD ranges.

This above makes it's a portable general purpose X-ray system. OXOS is marketing the M01 system for use by only qualified or trained clinicians on adult and pediatric patient populations for diagnostic static X-rays and serial radiographic exposures. The DDR feature was discussed at the first presentation and is specifically for use on extremities. It is not intended to replace any

radiographic systems that allow variable currents and voltages in a range that is necessary for quality images or the exposures created for other types of exams. The M01 is a point of care imaging system, and it permits the operator be 12 feet away while it's being used. The system is designed to be a mobile unit as opposed to being kept in a single location for an extended period of time. In other states, the device is used in ambulatory surgical centers, hospitals, urgent cares, skilled nursing facilities, nursing homes, long term care facilities, assisted living centers, home health providers and particularly for home bound patients.

RPS Staff and selective RAC Members had follow up questions from the first presentation specifically regarding Dynamic Digital Radiography (DDR), which is the serial exposure feature of the system. This serial imaging modality takes high speed single X-rays in quick succession, and OXOS believes it is distinct from fluoroscopy. The most distinctive aspect is that DDR takes single, diagnostic still X-rays in sequence, as opposed to fluoroscopy which integrates multiple images into a video sequence. DDR is a means of providing dynamic imaging for diagnostic purposes of motion. OXOS stated that fluoroscopy is not dynamic digital radiography.

Following the two OXOS M01 System presentations, a review of all supportive documents, and input from the Radiation Advisory Committee, RAC made a recommendation (by vote) that there should be exemption conditions for the sale-use of the OXOS M01 Imaging System in Oregon. Conditions include that it will need a 30-centimeter SSD, by ruler for purchasers of the machine. Since the M01 system is "fluoro-like" it must adhere to OAR fluoroscopy rules. The M01 System is to be used only in surgical settings--- no hallways or patient rooms, and is for extremity use only. A stand will have to be sold with the device. Applications training will also need to be included to use the stand with the device.

[Note: The State of Colorado Administrative Rules are comparable to RPS OAR's regarding fluoroscopic devices and requirements specific to use less than/more than 7 consecutive days.]

M01 system operators must follow RPS OAR rules concerning fluoroscopy supervision and use. Registrants will be expected to reinforce operator rules. If the M01 system is used as a portable device, it can only be used in the single capture mode as an x-ray device. When used in surgery requiring fluoroscopy-like capability, the M01 system will be permitted to be used in the DDR mode.

RPS will formalize an exemption letter (with conditions) to OXOS Medical Inc.

Fujimi Corp. – Kanomax Model 3550 Annular Flow Ion Mobility Classifier

No Fujimi representatives attended the RAC meeting. RPS Staff member Brent Herring provided a briefing about the exemption request concerning a Kanomax Model 3550 Annular Flow Ion Mobility Classifier. It is used to remove any electrostatic charge build up on an object. The device ionizes molecules near charged objects to effectively remove electrostatic charges accumulating on an object. The output radiation of the soft X-ray model has a peak wavelength of 0.2 nm with an energy between 3 and 9.5 keV, which is categorized as a "soft" X-ray. Soft x-rays do not easily penetrate solid materials and are attenuated using relatively thin shielding. The user does not have access to direct radiation when using the device. It includes a safety lockout and dual indicators for X-ray module power and active emission. Fujimi believes that granting the exemption will not result in an undue hazard to the public worker health and safety property or material security.

Fujimi requested an exemption to all industrial device OAR rules, including the general requirements for device registration, industrial radiography operators, radiation safety requirements, reports, notices to workers, radiation safety for all X-rays standards for radiation protection and safety for industrial X-ray operators.

RPS staff looked at the documentation Fujimi Corp. submitted. RPS noted that it is normal for a Registrant or Licensee to make an exemption request to specific OAR requirements, not for an entire rule division. RPS staff question the intention. Is the intent to not register this x-ray device because of its characteristics and/or to be exempted from routine inspections?

An RPS staff review found that the Fujimi /Kanomax documents reinforce there is a potential harm from exposure to the Kanomax soft x-rays. The device documents indicate that a device owner should build their own protective enclosure and gives instructions about what kind of shielding devices are to be used. The device manual lists several warnings for using the device, including having a controlled area sign near the device; seeking treatment from a physician if there is an exposure to x-rays during operation of the device; a warning that soft x-rays are harmful to humans; that before using the device, to always check that there is no radiation leakage; and that there should be a soft x-ray shielding area or enclosure. Based upon the RPS staff presentation, RAC took a vote recommending that the requested exemption not be granted.

Rulemaking

RPS Licensing Manager Todd Carpenter presented the below radioactive material licensing OAR amendments to RAC explaining that, due to RPS-Nuclear Regulatory Commission (NRC) rule compatibility requirements (as an Agreement State), RPS is obligated to make the rule amendments; that RAC approval is not

needed. Most of the rulemaking was administrative in nature (i.e., to change addresses where documentations are submitted, change contact phone numbers, who to notify, or which agencies that require collection of documents). Amended rules include OAR 333-105-0560, OAR 333-105-0700, OAR 333-105-0740, OAR 333-113-0210, OAR 333-116-0680, OAR 333-116-0690, OAR 333-116-1000, OAR 333-116-1015, OAR 333-118-0070, OAR 333-120-0450, OAR 333-120-0700, OAR 333-120-0710, OAR 333-121-0320, OAR 333-125-0025, OAR 333-125-0080, OAR 333-125-0120, OAR 333-125-0125 and OAR 333-125-0180.

Todd also shared the Statement of Need and Fiscal Impact document with RAC.

Proposed Oregon Board of Medical Imaging (OBMI) rulemaking for extremity computer tomography machine (CT)- Brent Herring- RPS Lead X-Ray Program Worker

Based upon a facility request, the Oregon Board of Medical Imaging (OBMI) is exploring implications to their OAR 337-010-011(1)(b) which states that those who operate an extremity computer tomography machine do not have to obtain a CT credential on their license. [Note: RPS rules state that CT X-ray systems shall be operated by personnel authorized by the OBMI.]

The possible rule change is related to OBMI's definition of what constitutes being an extremity CT machine. The current rule states that is a machine that's specifically designed with a maximum setting of 120kVp at 60 mAs to perform CT exams on extremities only. CT on extremities is defined as the start of the distal end of the femur along the entire lower extremity and upper extremity is from the distal end of the humerus to the hand.

OBMI's is considering a rule change to increase the technique from 120 kVp at 60 mAs to 140 kVp at 200 mAs. In addition, the term "distal" would be removed, so that extremity would be considered to mean "hip to toes".

RPS staff have concerns about the basis to increase the technique to 200 mAs for an extremity CT and the removal of the term "distal". If CT is considered to be imaging above the knee, it is actually including the pelvis which is not considered an extremity.

Based upon the Brent's presentation, the RAC recommended that RPS communicate its' concerns to OBMI during the rulemaking process, because the proposed language may not be in the best interest of the patients.

Emergency Preparedness/Response-

Hillary Haskins provided an update regarding the below topics:

Puget Sound Naval Shipyard – Nuclear Core Compartment Inspection and tour

RPS staff members Hillary Haskins and Rich Patterson were part of a State of Washington-Oregon inspection team that verified/located vessel "heat maps" to measure the highest radioactive areas. The Navy also provided a full tour of the facility.

FEMA – Evaluated Dress Rehearsal Drill (9/13/2022)

RPS successfully switched to a CBRN (chemical, biological, radiological and nuclear) Responder application. It is used to track RPSs' field teams and samples taken at a radiation incident. RPS drilled at Blue Lake, Troutdale, OR and received positive feedback from the on-site FEMA evaluators.

Radiation Operation Support Specialist (ROSS) –

Currently there are two certified ROSS members in Region 10 (Idaho, Oregon, Washington & Alaska). The ROSS program helps create a group of radiation professionals that can be integrated into the Incident Command System (ICS) management system and field response efforts for state radiological events. The ROSS program invites first responders and medical Health Physicists to receive radiation training and radiological incident management orientation so they be a part of increasing personnel to strengthen state radiological event responses.

Ukraine Nuclear Power Plant Monitoring

The International Atomic Energy Agency (IAEA) sent a team to Ukraine evaluate and monitor radiological concerns related to the Russian-Ukrainian conflict. The Environmental Protection Agency (EPA) continues to use its' long-standing 24/7 one-hundred forty RadNet stations to monitor US radiation levels. Department of Health staff from Alaska, Oregon, Washington and Idaho have also initiated a regular monthly interstate teleconference to address potential Russian-Ukrainian radiation monitoring and risk communication issues.

New Business

Clarification of the next date of the Radiation Advisory Committee meeting. Meetings are scheduled on the second full week of the month on Wednesday.

Public Comments

No comments

Next meeting is scheduled for February 15, 2023