Radiation Advisory Committee Meeting February 14, 2024 Hybrid Meeting

Attending:

<u>Radiation Advisory Committee Members</u> David Hamby – OSU Emeritus in Health Physics & Nuclear Engineering Saulo Sousa Melo – Oral Maxillofacial Radiologist at OHSU School of Dentistry Robert Berry – Nuclear Medicine Lead & Radiation Safety Officer at Providence Portland Medical Center and East Portland Alicia Zambelli – Veterinarian & Co-owner of Fern Hill Veterinary Care in Happy Valley Barbara Smith – Portland Community College Instructor in Radiologic Technology, Retired Mandy Henrikson – COO of Palm Beach Tanning

Radiation Protection Services

Alex ParkerTodd CarpenterHillary HaskinsMichelle MartinPatty ThompsonTom MynesDaryl Leon

Erin DeSemple Rama Wusirika Lee Lind David Howe Judy Smith Rich Patterson

<u>Guests</u>

André Ourso – Center for Health Protection Administrator Thomas King – Oregon Board of Medical Imaging Linda Kihs – Oregon Dental Assistants Association Christine Holmes – Director of Diagnostic Imaging at Sky Lakes Medical Center

Approval of the Minutes from October 11, 2023 – Barb Smith

Motioned by Bob Berry Second by Mandy Henrikson Minutes approved.

Re-Appointment of 2024 - 2027 RAC Members – David Howe

- David Hamby Oregon State University Emeritus in Health Physics and Nuclear Engineering; CEO Renaissance Code Development
- Robert Berry Nuclear Medicine Lead and Radiation Safety Officer at Providence Portland Medical Center
- RAC Members unanimously approved their re-appointments.

Program Updates – David Howe

- One vacant Environmental Health Specialist 3 (EHS3) position
- New SEIU contract increases payroll expenses due to two cost of living adjustments during this contract period; RPS budget is stable (cost vs. revenue) for existing staff.
- Formal budget analysis pending with fiscal staff (June 2024) to determine capability of filling vacancy.

2023 RPS Annual Summary Report

X-Ray Inspections 2023 Year in Review				
Year	Facilities	Machines	Tubes Inspected	Number of
	Inspected	Inspected		Violations
2023	987	3,536	3,547	255
2022	556	2,074	2,117	213
2021	326	1,345	1,422	91

Electronic Product Program Review – Hillary Haskins

*Increased numbers reflect pandemic effect and new EHS3 inspectors doing independent inspections

2023 Violation Summary (Top Three Violation Types):

- Operator's protected area shall provide visual indication of patient during exposure.
- Operators must complete machine specific applications training.
- Machine must be capable of functioning at manufacturer's intended specification.

2023 Exemption Summary:

- (31) exemptions processed in 2023
- (11) were for veterinary clinics wishing to user Computed Tomography (CT) machines

<u> Tanning Program Review – Hillary Haskins</u>

- Multi-year review: (92) inspections completed in 2023; (99) inspections completed in 2022; (22) inspections completed in 2021.
- <u>2023 Violation Summary (Top Three)</u>: Timer not checked annually; Emergency stop not checked annually; Trained operator not present.

Radioactive Material Licensing Review – Hillary Haskins

2023 Summary

• <u>103 Licensing Actions were completed including: (</u>37) Change Radiation Safety Officer or Authorized User; (29) Renewals; (11) Terminations; (10) Add/Remove source; (7) Change address or Company name; (3) Financial Assurance; (2) New; (4) Other.

2023 Inspections and Violation Summary

- 93 inspections were performed
- 20 facilities were issued Notices of Violation (NOV)
- NOV Severity Level count: None for Level 1; None for Level 2; 8 for Level 3; (18) for Level 4 and (7) for Level 5
- Types of NOV's: (8) for Annual audits not conducted; (5) for Dose Calibrator, Medical Events not reviewed; (4) for Leak tests not performed; (4) for no HAZMAT initial/3-year refresher training; (3) for no Equipment calibration; (3) for no Six-month

inventory/postings; (2) for no Radiation Safety Training; and (7) for miscellaneous violations

2023 Emergency Response/Incident Review – Hillary Haskins

- There were a total of 67 Incidents/Allegations in 2023, including: (17) Scrap monitor alarms; (17) Waste monitor alarms; (12) Medical events; (7) Complaints/allegations; (4) Theft/damaged sources; (3) Pranks; (2) Accelerator patient overdoses; (5) Other
- <u>Highlighted Incidents include:</u> a Stolen gauge (and recovery); Lu-177 found in various waste facilities which appears as plutonium on older Radioisotope Identifiers (RIIDs); a Lu-177 patient passed away withing 24 hours of receiving treatment; and a Therapy/Accelerator incident involving a patient being treated on the wrong area with multiple fractions

2023 Training and Conference Review – Hillary Haskins

- <u>RPS selected staff attended Training included:</u> Radiological Emergency Response Operations (RERO); Nuclear Regulatory Commission (NRC) courses; Incident Command System (ICS) courses; State-delivered NRC Licensing (G-109) and Inspection Procedures (G-108) course.
- <u>RPS selected staff attended Conferences included:</u> Radiological Assistance Program (RAP) – US Department of Energy;_Organization of Agreement States (OAS) Annual Meeting; Conference of Radiation Control Program Directors (CRCPD) Annual Meeting
- <u>RPS staff was also the hosting agency for an NRC Intern</u>

2024 Priorities – David Howe

- 1) Complete a successful NRC Periodic Meeting (informal audit)
- 2) Continue professional development opportunities for RPS staff
- 3) Finalize the "2024 PHD State Radiological Emergency Response Plan"
- 4) Acquire personal electronic dosimetry for Emergency Response Team members
- 5) Fully integrated databases for licensing, inspections and incidents.

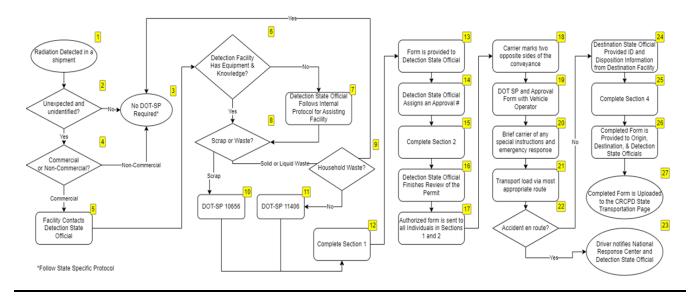
Exemption/Rule Updates

• Exemption requests for using Computed Tomography (CT) in veterinary practices - David Howe

The RPS vetting process includes: 1) Confirming a shielding study, physics report, and floor plan with proposed use of machine 2) Approving all new operators-only Certified Veterinary Technicians and Veterinarians can be operators 3) Confirming professional licenses with the Oregon Veterinary Board 4) Confirming completion of vendor

applications training and 5)_Confirming completion of Medical Imaging Consultants (MIC) CT training.

- Oregon Department of Energy (ODOE) Waste Rules Update Hillary Haskins
 - ODOE is updating their rules due to inappropriate dumping of "fracking" waste in Arlington, Oregon
 - Up until recent rule changes, radioactive waste facilities were required to dispose of the waste within 7 days. This is problematic because the West Coast only has 2 radioactive waste brokers that come through Oregon quarterly.
 - New ODOE rules allow reorganization of exempt quantities. Facilities that use a plan to identify metabolized medical treatments (i.e., lutecium and iodine) can now do disposal themselves.
- Department of Transportation (DOT) Special Permit Form Update Hillary Haskins



DOT-SP Process Overview

- RPS Duty Officers use the above chart when responding to waste and scrap portal alarms which shows the process to get a waste load returned to its point of origin.
- RPS creates an annual report to the Department of Transportation regarding all s issued permits.

Discussion of Need for Dental CT Documentation by Oral or Maxillofacial Radiologist – David Howe/Dr. Sousa Melo

 Dr. Sousa Melo discussed the merits of cone-beam CT scans being read by a well-versed dentist, or ideally, by an Oral and Maxillofacial Radiologist, including comprehensive documentation of the findings

- Dr. Sousa Melo's concern is that there is a significant difference in the required documentation for medical CBCT's, versus dental CBCT's. This is an issue that the Oregon Board of Dentistry (OBD) rules govern.
- Based upon Dr. Sousa Melo's presentation, the RAC requested he draft a rule amendment recommendation letter to be sent to OBD regarding clarification of who can perform CBCT image reviews, required training and documentation.

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Discussion of Rectangular vs. Circular Collimation Possible OAR 333-106-0325 Revision – Michelle Martin/Dr. Sousa Melo

- Rule 333-106-0325 states in (2)(a) that if the minimum source-to-skin (SSD) is 18 centimeters or more, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than <u>7 centimeters</u> or (2)(b) if the minimum SSD is less than 18 centimeters, the x-ray field, at the minimum SSD, shall be containable in a circle or rectangular cone having a diameter of no more than <u>6 centimeters</u>
- RPS rules stipulate that if rectangular collimation is used, then a position indicating device (PID) must be used for each exam due to the high rate of x-ray cutoff from rectangular cones.
- Dr. Sousa Melo advised that studies show using rectangular collimation drastically reduces the amount of radiation the patient receives. He also shared that the dental industry is shifting toward using rectangular collimation, which supports what he is currently recommending.

Further discussion led to the suggestion of sending out an RPS Information Bulletin to dental practitioners and vendors about the merits of using rectangular collimation. Dr. Sousa Melo agreed to work with RPS staff to compose an information bulletin. It was noted that the use of dental Hand-held x-ray devices should also be addressed.

• MQSA Information Bulletin 2023-02 Re: New Dense Breast Tissue Notification Language – Michelle Martin

Pending FDA rules do not align with current RPS OAR notification language.

To address the issue, RPS released an Informational Bulletin (2023-02) on October 12, 2023 giving mammography services facilities the option to use existing OAR language or the new FDA notification language until the new FDA rules become effective, September 10, 2024. At that time all mammography facilities will be required to use the FDA notification language.

• Required Tanning Facility Operator Training Update- RAC Member Mandy Henrikson, COO of Palm Beach Tan

• There are four RPS-approved Tanning Operator vendor trainings, they are:

- 1. International Smart Tan (nationwide)
- **2.** Sun is Life (nationwide)
- **3.** National Tanning Training Institute (nationwide)
- 4. Oregon Tanning Certification (Oregon specific trainer)
- Mandy recommends RPS evaluate training programs periodically.

Legislative Bill Update- David Howe

• During the 2024 Short Session (Feb 5th to March 10th) there were no legislative bills presented that affected RPS.

Rulemaking Update-Todd Carpenter

- <u>Oregon Health Authority now requires Equity Statements in rulemaking</u>. Amended rules need to consider all Oregonian needs (i.e., not focus on one geographic, social-economic area)
- X-ray Signage vs. Radiation Area Labels-

There has been confusion by Registrants regarding which type of signs need to be posted. "Radiation Area" means individuals exposed to radioactive materials and receiving a dose equivalent in excel of the following limits:

"Radiation Area" – receiving a dose equivalent in excess of 0.005 rem in one hour at 30 cm from radiation source or any surface that the radiation penetrates

"High Radiation Area" – receiving a dose equivalent in excess of 0.1 rem in one hour at 30 cm from radiation source or any surface that the radiation penetrates

"Very High Radiation Area" – receiving a dose in excess of 500 radiation in one hour at one meter from a source or any surface that the radiation penetrates

- Potential Rulemaking Regarding Non-Radiological Practitioner Fluoroscopy Training
 - Rule OAR 333-106-0205(4)(c) changed the type of required fluoroscopy supervision to "under the personal or direct supervision of a radiologist or nonradiologist..." RPS is proposing an additional rule amendment that all nonradiologist practitioners will need fluoroscopy training.
- Potential Rulemaking Items
 - OAR 333-119-0100(4) includes that a tanning bed has to be serviced by a licensed electrician. There is a need to clarify that a licensed electrician is not required for plugging the tanning device into an electrical outlet.
 - OAR 333-106-005(108) "supervision" language amendment- need to add the

term "direct" so that it states: "Supervision" means "the supervising individual routinely reviews and monitors, or <u>directs</u>, the work being performed".

- OAR 333-106-0025- repeal the state "notwithstanding sections (1), (2) and (3) of this rule about being a general licensee for out-of-state radioactive material under specific license may be brought into the state for use at temporary jobsites only under the provisions of OAR 333-102-0340 regarding the use of out-of-state x-ray machines. This is 30–40-year-old language. Now a company has to notify RPS that a machine is being brought in from out-of-state.
- Current OAR states that non-radiologist practitioners, who are physically present in the room during fluoroscopy use, are required to have Authority approved fluoroscopy training if the non-radiologist practitioner is operating a fluoroscopy machine or supervising a fluoroscopy operator (Radiologic Technologist)

OAR 333-106-0205: add the term "personal" supervision to the rule for non-radiologist practitioners as underlined below:

 Radiologic Technologist may operate fluoroscopic equipment under the personal or direct supervision of a radiologist or <u>personal</u> supervision of a non-radiologist practitioner... [Note: RPS needs consult with Oregon Board of Medical Imaging to ensure rule compatibility.]

Emergency Preparedness/Response Update- Hillary Haskins/Michelle Martin

- RPS Emergency Response Team (ERT) members participated in the FEMAevaluated, February CGS Hanford Dress Rehearsal "Ingestion Pathway" Exercise. The drill included sampling of milk, soil, vegetation, water and air. The "Full" Evaluated Exercise takes place in March.
- Incidents:
 - (4) Therapy Events have occurred at different facilities Michelle
 - Dates range from October 2023 to February 2024. To date, one investigation has been completed. This incident involved the wrong site being treated due to not following protocols. Treatment was based off of using a scar as a marker, versus tattooing which the patient refused. From the first to third treatment the scar healed and they went off a different scar resulting in the wrong site being treated.
 - Three other investigations are still ongoing and they also involve wrong sites being treated.
 - <u>Tuality-Hillsboro Medical Center Exceeding the Annual Dose Limit –</u> <u>Hillary</u>

A Final Order (\$15,350 Civil Penalty) was issued for 32 offenses

 This case involved a Fluoroscopy physician who received more than 5 Rem in 2020 but who was allowed to continue performing fluoroscopy procedures. The initial dosimetry report showed 322.456 Rem, but it was recalculated to actually be 21.667 Rem. The Registrant (hospital) did not contact RPS about the overexposure within required OAR specified notification time frames.

OHSU Microsphere "Underdosing" Medical Event - Michelle Y-90

- This Selective Internal Radiation (SIR) event occurred at OHSU on September 21, 2023. The prescribed dose was 7.2 mCi, but the delivered dose was 5.6 mCi. The procedure involved Y-90 resin SIRspheres used to treat liver tumors. Y90 is a Beta emitter with a half- life of 64 hours and the microspheres are similar in size to red blood cells. The SIRspheres were delivered to the hepatic artery and carried by blood to the tumor microvasculature. The Interventional Radiologist (IR) underdosed the patient by leaving >20% of the SIRspheres in the tubing/syringe. The Corrective Action (CA) was to change the procedure to require a minimum flush amount of 30cc.
- Metro Interagency Agreement Revision Todd Carpenter
 - RPS revised the Metro Waste Transfer Station Interagency Agreement (IAA) to provide only radiation training of their hazardous material technicians.Radiation Training is needed due to household medical waste setting off Metro portal monitors more frequently.
- ODOE/RPS Interagency Agreement for RPS ERT Training- Todd
 - RPS renewed its' ODOE IAA in support of RPS ERT staff training/drilling in order to have radiological emergency response capabilities for ODOE.
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 - ODOE/RPS First Responder-Receiver Training Todd
 - RPS is also renewing its' ODOE IAA to provide radiation training services to First Responders and First Receivers along ODOE radiation transportation routes for accidents and contamination events.
- 2024 State Radiological Emergency Response Plan- Todd
 - Oregon Emergency Management (OEM) has an emergency procedure for all types of hazards. Oregon Health Authority has an Essential Support Function (ESF) role which means that RPS provides radiological emergency response, coordination and mitigation. The "2024 State Radiological Emergency Response Plan" is being designed to identify phases of a response. It will offer resource information (i.e., state and federal partner agencies), but does not provide step-by-step instructions on how to take care

of a spill or contamination. The plan is aligned with the National Incident Management System (NIMS) which allows all participants to use the same verbiage so there is no confusion when instructions are given.

- Health, Security and Preparedness Response Program (HSPR) Monies for ERT Member Electronic Dosimetry Purchase – Todd
 - HSPR received federal grant money and is sharing it with RPS. Monies have been used, based on a collaborative purchase agreement, to obtain 18 personal emergency radiation detectors/dosimeters (Thermo Scientific Radeye – Personal Dose Rate Meters)

New Business

- 2024 Mandatory RAC Member Training David Howe
 - There are 4 required trainings that are accessed through Workday

PUBLIC COMMENTS:

- Dr. Sousa Melo made a suggestion to discontinue the use of thyroid collars for intraoral x-ray exposures
 - The American Dental Association (ADA) released a paper on clinical recommendations and regulatory considerations. ADA is no longer recommending the use of thyroid shielding during diagnostic intraoral panoramic and CBCT imaging procedures and that their use should be discontinued as routine practice. ADA based their recommendation on a paper release by the American Academy of Oral Maxillofacial Radiology in 2023. An RPS rule amendment of OAR 333-106-0325(D) would be necessary in order to remove the requirement for using pediatric patient thyroid collars. [Note: RPS has based its' OARs on IAEA rules. As such, RPS would need to review IAEA rules in consideration of any potential OAR modifications].
- Dr. Sousa Melo also expressed a concern about handheld dental x-ray devices not being held correctly by the operator.
 - Dr. Sousa Melo stated that device operators are not holding hand-held units perpendicular to the shield which means the operator is getting unnecessary exposure. He shared that OHSU dental students are advised to wear a leaded apron for added exposure protection, due to hand-held device built-in back scatter shielding having positional limitations during device operation.
 - RPS advised RAC members that there are OARs regulations pertaining to the sale/use of handheld dental x-ray devices in Oregon, including, but not limited to, requirements for permanently attached device backscatter shielding, device operator specific applications training, and presentation of training certificates during RPS on-site inspections.

• Thomas King from the Oregon Board of Medical Imaging (OBMI) stated that they have adopted a rule for hybrid imaging operators (OAR 337-010-0017) which relates to a recently installed Biology Guided Radiotherapy (BGRT) machine at Salem Hospital. BGRT machines incorporate CT radiation therapy and nuclear medicine as therapy modalities.

Announcements

- Next meeting scheduled for June 12, 2024
- Meeting adjourned at 1:32 pm