

Radiation Advisory Committee Meeting (RAC)

June 14, 2023

Attending:

Radiation Advisory Committee Members

David Hamby – OSU Emeritus in Health Physics & Nuclear Engineer

Dennis Wood – Medical Physicist at Bay Area Hospital, Coos Bay

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

Garrett Frey – Safety Manager, Radiation Safety Officer @ KnifeRiver (Industrial)

Alicia Zambelli – Veterinarian & Co-owner of Fern Hill Veterinary Care in Happy Valley

Barbara Smith – Portland Community College Instructor in Radiologic Technology,
Retired

Radiation Protection Services

Alex Parker

Brent Herring

Todd Carpenter

Dong Lim

David Howe

Hillary Haskins

Michelle Martin

Guests

Thomas King – Oregon Board of Medical Imaging

Isaac Bailey – Oregon Health Science University

Celeste Winters – Oregon Health Science University

Anna Mench – Oregon Health Science University

Linda Kihs – Oregon Dental Assistants Association

Lori Horstman – Clinical Application Specialist with Xstrahl for Clear Choice Dermatology

Andrew Solinger, Lawyer – Clear Choice Dermatology

David Greene – Radiation Oncologist with Clear Choice Dermatology

Collin Blattner – Dermatologist with Clear Choice Dermatology

Liwei Zhang – Medical Physicist with Clear Choice Dermatology

Catherine Hess – Radiation Safety Officer, Legacy Health Systems

Approval of the Minutes from February 15, 2023

Motioned by Garret Frey

Second by Bob Berry

Minutes approved

Staffing

- Hillary Haskins is our permanent Field Operations and Emergency Response Manager.
- Currently have one vacant Environment Health Specialist 3 position. RPS will complete a budget evaluation to determine if there is adequate funding to fill the open position.

Budget

Fiscal Year 2023 – Budget Summary Ending March 31, 2023

| 3/31/2023 | | | | | |
|---|-------------------|-----------|-----------------|-------------|-------------------|
| Grant Title | Beginning Balance | Revenue | Accrued Revenue | Expenditure | Remaining Balance |
| RPS X-Ray Registration Fee | 74 | 3,251,204 | - | 2,815,177 | 436,101 |
| RPS Radioactive Materials License (RML) | -179,213 | 1,918,356 | - | 1,914,381 | -175,238 |
| RPS Tanning Device Registration | 59,967 | 356,474 | 10,580 | 227,292 | 189,148 |
| RPS DEQ School Disposal | 1,922 | - | - | - | 1,922 |
| RPS DOE First Responder Training | 19,249 | 15,000 | - | 6,149 | 28,100 |
| RPS Grain Analysis Lab Fee | -1,132 | 10,888 | - | 19,271 | -9,515 |
| RPS Metro Rad Mat Disposal | 70,353 | 18,400 | - | 3,715 | 85,038 |
| RPS DOE Emergency Response Training | -7,824 | 113,579 | - | 165,181 | -59,426 |
| RPS Mammography Fac Inspection PH23 | | 163,053 | - | 39,006 | 124,047 |
| RPS Mammography Fac Inspection PH22 | 243,568 | 289,755 | - | 330,479 | 202,843 |
| Total OF | -36,604 | 5,683,901 | 10,580 | 5,151,166 | 496,131 |
| Total GF | - | - | - | - | - |
| Total FF | 243,568 | 452,808 | - | 369,485 | 326,891 |
| Total All Funds | 206,964 | 6,136,708 | 10,580 | 5,520,651 | 823,021 |

Electronic/Tanning Inspections

- Inspector sign offs
 - Environmental Health Specialist 3 (EHS3) Sarah Brodesser is signed off to independently inspect chiropractic facilities.
 - EHS3 Rich Patterson is signed off to independently inspect chiropractic facilities.
- Inspections since February 2023 RAC meeting
 - 315 X-ray inspections (medical, dental, veterinary, therapy, MQSA and industrial)
 - 1157 machines
 - 1172 tubes
- Violation Summary
 - X-ray Facilities
 - 22 facilities failing to register x-ray machines.
 - 6 registrants for equipment not being capable of functioning at the manufacturers intended specifications.
 - 6 registrants where the dental operators did not complete machine specific applications regarding hand-held x-ray device training.
 - Tanning Facilities
 - 2 for facilities or devices not being maintained in a sanitary state.
 - 2 for bed timers not being checked annually for accuracy.
 - 2 for emergency shut-off switches not being tested annually.

Radioactive Materials Licensing

- February 1 to May 31, 2023 activity
 - 23 Inspections completed
 - 55 Licensing Actions completed
 - 8 Incidents closed
 - 22 Incidents remain open
- February through May Incidents and Responses
 - Asante Three Rivers Medical Center – Spears Cancer Center in southern Oregon. Their qualified medical physicist (QMP) went on medical leave, and they only had a resident medical physicist (MP), not certified by an accredited radiology board, available to treat patients. RPS advised the licensee they were violating OAR 333-123-0015 and directed the registrant to not begin treating any new patients until corrective actions occurred. RPS allowed Spears Cancer Center to continue treating patients who were undergoing therapy so as to not interfere with their therapies. The immediate corrective action was to have a board-certified QMP from their other medical facility supervise the non-certified MP and to initiate a full audit of the non-certified MP's patient treat plans and other formal work. RPS also granted Spears Cancer Center one month to hire a QMP to replace the one on medical leave. Spears Cancer Center continues to work on completing the corrective actions.
- 9 Portal Alarms
 - Most were associated with Lutetium 177 (Lu 177), a radioisotope used for prostate cancer treatments. Two radioisotope brands are used including Pluvicto which has a potential for a metastable byproduct, with a longer half-life of over 120 days due to increased capacity and Luta Thera which has a half-life of 7 days.
 - There are three hospitals that currently offer Luta Thera treatments. As a post-treatment control measure, patients are discharged wearing adult diapers. It appears inadequate home care instructions were given which caused "hot diapers" to be disposed/transported to waste facilities. RPS is consulting with the hospital Radiation Safety Officers to devise better home care instructions to keep the diapers out of the waste facilities until they are at a safe activity level for disposal.

2023 Training and Conferences

- Training
 - NRC on-line and in person
 - Oregon is hosting an NRC Inspection Procedures course in July for five RPS staff members/students, plus State of Washington and Nevada students.
 - Incident Command System (ICS-300 and 400) August courses- two RPS staff attending

- Mammography
- Conferences attended in person and on-line
 - Conference of Radiation Control Program Directors (CRCPD) will be in May in Houston, Texas with Todd Carpenter and Hillary Haskins attending.
- 2023 Organization of Agreement States Annual Meeting will be in August in Seattle, Washington with David Howe and Hillary Haskins attending.
- FEMA Radiological Emergency Preparedness Course will be in Monterey, CA with Hillary Haskins and Todd Carpenter attending.

Exemptions/Rules/Statutes

- **Salem Health Hospital – Biology Guided Radiotherapy (BGRT)**
 This is new technology approved by the FDA in February 2023. Positron Emission-Computed Tomography (PET/CT) and radiation therapy have been combined into one machine, so the patient doesn't have to leave the table. Both procedures are commenced at the same time. Operating BGRT combines both RML and X-ray regulations. Current Oregon Administrative Rules (OAR) will require two operators, one for the PET/CT and the other for radiation therapy element of the machine. PET/CT operators must adhere to Oregon Board of Medical Imaging (OBMI) rules which requires an operator to be licensed as a Radiologic Technologist – Nuclear Medicine (RT-N) or Certified Nuclear Medicine Technologist (CNMT). The radiation therapy operator is required to be licensed as a Radiological Technologist – Radiation Therapy (RT-T).

Under OAR 333-116-0880 radioactive materials rules, a Radiation Therapist with the credentials RT-T can run a PET/CT machine given that they are working under an Authorized User, have basic radiation safety training, and 40 hours of specific training for PET. It's unclear what additional education and training will be required to demonstrate competency. RPS is reaching out to other states to determine if therapists are allowed to operate a PET/CT machine and/or what is their criteria for approving them. Oregon Board of Medical Imaging is also being consulted for operator criteria.

Veterinary Referral Center of Central Oregon – Radiation Safety Course

[Note: This is not an exemption request, but an update]. Veterinary Referral Center of Central Oregon submitted an in-house radiation safety training course for their veterinary assistants. The veterinarians will teach the course and administer the quizzes and tests. The course incorporates a course syllabus, a comprehensive PowerPoint presentation, videos, quizzes, and a final test. RPS staff have reviewed/approved the course as being adequate training to meet RPS OARs for vet assistants.

OHSU – National Primate Research Center

OHSU National Primate Research Center submitted an addendum to their 2012 exemption to OAR 333-106-0370 to add new operators to operate Computed

Tomography (CT) machines. RPS notified OHSU the approval process now requires additional training. The exemption request is for veterinarians (DVMs), Certified Veterinary Technicians (CVTs), or graduate research assistants to be operators to meet the training requirements of OAR 333-106-0055 and operator requirements within OAR 333-106-0370. DVM's and CVT's will be required to complete vendor training and a Medical Imaging Consultants (MIC) CT Cross Training course to be approved by RPS as CT operators. Research assistants are not allowed to be operators because they need more education and training listed in OAR 333-106-0055. RPS is waiting for documentation of DVM and CVT completion of the required training to move forward. Nothing has been approved at this time.

OHSU – Bone Density Exemption Request

This exemption for OAR 333-106-0035 for use of a bone density machine to set up a quality assurance (QA) protocol for bone density studies. During the process of reviewing this exemption OHSU's Institutional Review Board (IRB) stated that the request did not fall under their protocols because it was setting up a QA program, not performing research. RPS asked the requesting researcher to contact OHSU's lead Health Physicist, to figure out another way to obtain this data. The researcher is communicating with the IRB to determine another QA method that will not expose individuals to unnecessary radiation.

Skin Vet Clinic – Exemption Request for Mobile CT

Skin Vet Clinic specializes in dermatology and ear care for cats and dogs. The exemption to OAR 333-106-0370(1) requests to use a Xoran VetCAT machine for skull CT's. The machine is on wheels but will only be used in one room. When not in use, it will be wheeled out of the room and stored in another room or hallway. The shielding report is currently being reviewed by RPS staff. The physics report looks adequate. The one proposed operator is licensed with the Veterinary Board and has completed vendor training and the MIC CT Cross Training course. If the shielding report is adequate, there should not be a problem for RPS to approve this exemption request.

- Motion to recommend approving the exemption by Alicia Zambelli
Second by Bob Berry
Motion approved

Superficial Radiotherapy – Radiant Xstrahl Model

RPS is reviewing OARs for applicability to this new technology. The Radiant Xstrahl Model is a new device in Oregon that uses superficial radiotherapy and superficial brachytherapy modalities to treat skin cancer. Electronic brachytherapy is used to treat cancers that are deeper in the body. Electronic brachytherapy has a shorter skin to source distance, which is less than 6 centimeters. However, radiotherapy uses an applicator that is 6 to 10

centimeters. Brachytherapy involves fewer fractions---one to two per week. Radiotherapy involves a lot more fractions, but at a lower dose. RPS has determined that the same supervision requirements would apply to both radiotherapy and electronic radiotherapy.

Clear Choice Dermatology – Exemption Request

- Clear Choice Dermatology treats skin cancer patients in Warrenton, Oregon. Dermatologist Dr. Blattner, is the treating physician doing the patient treatment planning and consultation with Dr. Greene, a Board-Certified Radiation Oncologist, licensed in Oregon, but based out of California; and Liwei Zhang, an Oregon Licensed Medical Physicist.
- Clear Choice Dermatology submitted an exemption request based on OAR 333-123-0135. It states that an authorized user (i.e., Dr. Blattner) must provide personal supervision of the superficial electronic brachytherapy operator (i.e., a Radiation Therapist) during the patient’s initial treatment when activating the X-ray tube; and provide direct supervision of the superficial electronic brachytherapy operator for all subsequent treatments. The definition of “personal supervision” means to be in the treatment room, “direct supervision” means to be in the building, and “general supervision” means being off-site, but available by telephone.
- The current practice is when a patient is diagnosed with skin cancer, Dr. Blattner discusses with the patient their options and alternatives. If the patient is a candidate for radiation, they are referred to Dr. Greene for consultation. If the patient elects to proceed with radiation, Dr. Green writes an initial radiation prescription and clinical treatment plan. The prescription is then input into the treatment planning console of the Xstrahl machine. The prescription is subsequently second checked against the Medical Physicist’s QA process. A final approval of the prescription in the treatment planning software console is done by Dr. Greene. The initial treatment is then delivered to the patient by the operator, under personal supervision of Dr. Blattner and subsequent treatments are completed, via direct supervision by Dr. Blattner.
- Clear Choice Dermatology is requesting an exemption to OAR 333-123-0135 for Dr. Blattner to provide general supervision of the operator (RT) during administration of all treatment fractions subsequent to the initial treatment. However, OAR 333-123-0135 for superficial electronic brachytherapy requires that the authorized user (Dr. Blattner) must provide personal supervision for the patient’s initial treatment and direct supervision (versus general supervision) during all subsequent treatments.
- Dr. Blattner has a Superficial Electronic Brachytherapy (SEB) machine located at his Warrenton clinic. Dr. Blattner is an associate with at least 5 other locations spanning from The Dalles to Sandy, to Hillsboro, to Warrenton, and Portland. Dr. Blattner is physically present in Warrenton to provide personal and direct supervision, as appropriate, in the Warrenton clinic on Thursday’s and Friday’s. This means he is currently compliant with RPS rules.

- RPS is missing key documentation to complete the review of this exemption request. For supervision requirements, RPS has not been able to confirm that Dr. Blattner's training meets RPS rules concerning radiation use and safety. RPS also has questions about the facility shielding information that was submitted. In addition, RPS needs more detailed information about the specifications for the machine, so it can be evaluated. Finally, RPS needs to know that the involved medical physicist is a qualified medical physicist (board certified).
- Another element of the exemption request is that the machine was installed without information being provided to RPS about the training requirements to be an operator. [Note: There is some confusion regarding the RPS X-ray registration application form that needs redressing.] That said, use of the machine was not evaluated/approved by RPS prior to its' first use and is therefore in violation of RPS rules because the machine and shielding studies were not reviewed and approved before commencing operation.
- At the conclusion of Clear Choice's presentation, RPS indicated that it would send Dr. Blattner a checklist of all the documentation required to be in compliance with RPS Oregon Administrative Rules.
- Lori Horstman, Clinical Application Specialist with Xstrahl, will send the machine specs and software information.
- RPS will allow Dr. Blattner to continue treating patients who are already in a course of treatment, despite not having completed the proper registration process. It is not RPS' intent, as a regulatory entity, to interfere with patient treatment. Dr. Blattner cannot accept new patients for superficial radiation therapy until the registration and training processes meet regulatory requirements.
- Dr. Greene stated during the pandemic, ASTRO and CMS both published a position paper and MS allowed reimbursement for using a tele-video as a means to provide "direct" supervision. An issue is that the site needs to be verified as the correct site. If Dr. Blattner does the initial biopsy and diagnoses it as skin cancer, or Dr. Green is looking at the biopsy photo and location on the patient's body through video link, both are looking at the visible lesion. Dr. Green said that ASTRO and CMS have taken the position that "eyes in the room" or "eyes via tele-video" are reimbursable as direct supervision. If a patient, for example, can't make it to Warrenton but can make it to another one of our clinics, that patient would still be allowed to receive their treatment provided that a direct tele-video link is there to determine that, the correct lesion is going to be treated. The goal is not to put this onto the technical staff, but rather to make it easier for Dr. Blattner to provide direct supervision or Dr. Green to provide a supervision role without being physically present in Warrenton for patient treatments.
- RPS asked how validation that tele-video direct supervision is taking place is determined. Dr. Greene stated that the electronic medical record will record the presence (login) of the attending physician and their presence on the tele-video link.

- RPS staff shared that there is not only a concern about treatment site and patient verification, but of having the authorized user in the building in the event of some type of medical situation arising during treatment. The concept of providing direct supervision via telemedicine, is not currently outlined in RPS administrative rules.
- Garrett Frey – Made a motion to recommend denying the exemption request for Dr. Blattner to be allowed to provide general supervision, versus direct supervision.
Saulo Sousa Melo – Seconded the Motion
Motion was passed to deny the Clear Choice Dermatology exemption request.

Legislative Bill Updates

- HB 2996 & HB 3223 A-15
 - The Oregon Board of Dentistry may require an applicant for certification to pass a written examination.
 - The board may accept the results of any examination that is
 - Administered by a dental education program and approved by the board by rule or an examination comparable that is administered by a testing agency approved by the board by rule and
 - The exam must be offered in plain language in English, Spanish and Vietnamese.
 - This act becomes operative on July 1, 2025
 - The Oregon Board of Dentistry shall convene an advisory committee of at least seven members to study the dental assistant workforce shortage and to review the requirements for dental assistant certification in other states
 - A majority of the members appointed to the committee must have experience working as dental assistants.

Rulemaking

- Proposed Future Rulemaking
 - Define radiation area relating to x-ray devices
 - Add the use of rectangular collimation to RPS rules
 - Recognize Naturopathic Doctors as a Non-Radiologist Practitioner (OAR 333-106-0005)
 - Require that a Non-Qualified Medical Physicist must be directly supervised by a Qualified Medical Physicist (OAR 333-123-0015)
 - Update and amend Division 123, X-ray therapy rules with CRCPD's suggested State Regulations Part X
- Temporary Rulemaking- Todd Carpenter
 - Remove the \$3000 fee cap for Reciprocity licensees (OAR 333-103-0030)

- David Howe asked RAC about their thoughts on adding the Oregon Board of Medical Imaging (OBMI) Executive Director (or designee) as an ex officio member of RAC since there are numerous overlapping rules/statutes. The change would require Legislative approval. RAC members expressed support of the idea.

Emergency Preparedness/Response

- There are upcoming Radiation Operations Support Specialist (ROSS) trainings
- Update on inspection & Response Equipment
 - Two Radioisotope Identification Devices (RIID)
 - X-ray test equipment
 - X-ray phantoms

New Business

- RAC Member Training classes
 - (4) 2024 mandatory classes for completion, via Workday including:
 - Preventing Discrimination & Harassment in the Workplace
 - Information Security Training: Foundations
 - Weapons & Violence Free Workplace
 - Public Records

Public Comments:

- None

Announcements:

- Next meeting scheduled for October 11, 2023
- Meeting adjourned at 1:03 pm