

RADIATION ADVISORY COMMITTEE MEETING
Minutes
February 12, 2020

Call to Order – Public Session

Donna Stevens, Chair, called the Radiation Advisory Committee (RAC) into public session on February 12, 2020 at 10:03 a.m. in Conference Room 1D of the Portland State Office Building.

Members Present:

Stevens, Donna, Chair	Krahenbuhl, Melinda, Ph.D.
Bremner, DMD, Fred	Smith, Barbara, ARRT
Cyman, DVM, Juliana	Young, Scott
Berry, Bob, Providence	Henrikson, Mandy, Vice Chair

OHA RPS Members Present:

Howe, David	
Carpenter, Todd	Lind, Lee
Wendt, Rick	Smith, Judy
Haskins, Hillary	

Guests

Phillis Collins, Facility Coordinator, VCA
Kristen Hixson, Assistant Hospital Manger, VCA
Karen Kline, Medical Director, VCA

Introduction of Members and Guests

Radiation Advisory Committee members, Radiation Protection Services (RPS) personnel and guests introduced themselves.

Approval of Minutes

Minutes from the October 9, 2019 meeting were sent to the members for their review, prior to this meeting.

Motion

Barbara Smith moved, and Dr. Fred Bremner, seconded the motion to approve the October 9, 2019 Radiation Advisory Committee minutes as written. The motion carried unanimously.

RAC Member Appointment Recognition

RPS Program Director David Howe gave a brief introduction and welcomed the two new members, Bob Berry and Melinda Krahenbuhl. David also expressed his gratitude to all the RAC members for their participation.

RPS Staffing

David reported RPS just initiated the hiring process, via the new “WorkDay” statewide software system, to fill an administrative support specialist vacancy. WorkDay covers everything from recruitments to payroll, but as a new system is also more tedious. All staff are working to become familiarized with it. David hopes to introduce the new administrative support specialist at the June 10th RAC meeting. This recruitment will give RPS 16 staff.

2019 RPS ANNUAL SUMMARY

RPS Budget (Power Point Available)

RPS Licensing Manager Todd Carpenter presented the RPS budget overview from July 1, 2019 through December 31, 2019.

He shared information about revenue versus expenses, including user fee accounts (X-ray program, Tanning program, Radioactive Materials program); federal contract (MQSA) and interagency grants (Oregon Department of Energy, CGS and Metro). Todd reported that the section’s ending balance of December 31, 2019 is projected to be \$1,393,289.

David pointed out that when a program has a significant ending balance within a biennium, it is vulnerable to being “swept” by OHA due to a lack of understanding that the funds are to be used for next biennium expenses

2019 RPS ANNUAL SUMMARY REPORT

Electronic Products Program

RPS Operations Manager Rick Wendt presented the Electronic Products Program 2019 Annual Summary. He reported on the overall scope of the X-ray program.

Rick reflected that last year was demanding due to more X-ray devices being inspected than the prior year. It was a successful inspection year because everyone worked collectively. In addition to X-ray device inspections, two staff are FDA-certified to perform 105 annual mammography facility inspections.

There were 892 inspections completed in 2019, with an additional 67 attempted inspections. [Note: Because routine inspections are unannounced, sometimes inspections need to be rescheduled; hence, attempted inspections].

RPS inspected 3,217 X-ray machines with 3,261 tubes. There is still a 652-facility inspection backlog which RPS has not been able to eliminate over the past several years. Oregon has a total of 12,171 tubes.

This past year, RPS issued 440 notices of violation. The top 5 violations include failure to register device, lack of adequate radiation use and safety training, failure to properly maintain dosimetry records, equipment not meeting manufacturer specifications, and inadequate gonadal shielding.

Registrants who have been issued a notice of violation are given a 30-day period to provide a written corrective action to RPS. If no corrective action is submitted, RPS increases the frequency of inspection and/or proposes a civil penalty.

Tanning Program

Rick presented the Tanning Program Annual Summary. There were 329 registered facilities in 2019 with 1,384 active devices. Two-hundred notices of violations were issued. The top violations included lack of operator training, sanitation issues, wrong lamps in devices, annual timer tests not conducted, annual emergency stop switch not tested, and trained operators not on site.

Radioactive Materials Licensing

RPS RML Lead Worker Hillary Haskins presented the Radioactive Materials Licensing Program Annual Summary. Hillary reported that RPS RML staff and managers had a successful Integrated Material Performance Evaluation Program (IMPEP) Periodic meeting with NRC representatives. The Periodic meeting is a “mini-audit” completed at the mid-point between full four-year IMPEP reviews. Performance indicators were reviewed. Despite staff turnover and cross-training time, all inspections were completed in a timely manner.

Hillary also briefed RAC on Severity Levels of inspection findings (level 1 to level 5). The 106 inspections completed in 2019 resulted in 36 Notices of Non-Compliance.

Emergency Response / Incidents

Rick reported that in 2019 there were 54 reported incidents, allegations and notifications, including:

- 15 medial events: 8 mis-administrations, 1 equipment failure after injection, 3 radiation safety issues, 2 annual doses exceeded and 1 use of an expired drug.
- 13 allegations: a CT operator with no license; a neutron generator being built in a Portland basement; a lack of oversight for radiation safety; using an XRF in public retail stores; and 6 Job Corp students being sent to the hospital for radiation exposure.
- 5 notifications: all pertaining to Hanford and Columbia Generating Station
- 3 theft/loss/damage events: 2 lost sources and 1 damaged gauge
- 2 tanning allegations: converting an UVA device to red light and lack of trained operators
- 15 requests for DOT Special Permits (SP) -scrap metal transport
- 1 request for DOT SP- radiation waste transport

Elekta Event Summary

David reported on the closure of an Abnormal Occurrence (AO) event involving the use of a high-activity Elekta Gamma Knife device. An RML management-staff team completed a comprehensive, long-term investigation of events surrounding the unnecessary irradiation of healthy brain tissue during cancer treatments of eight patients. The root cause was human error related to an Elekta manufacturer field service technician installing old software and mis-calibrating the hospital's QA application tool.

Elekta was cited for several violations (received \$3400 in civil penalties) relating to the field service technician's actions and licensing issues, and for not providing adequate notice of multiple state entries to perform manufacturer servicing of the device. Elekta did not contest the violations and civil penalties. As a part of the investigation, RPS required the manufacturer to provide a written corrective action plan.

RPS also offered Elekta formal recommendations based upon best practices, including to establish additional levels of software security; ensure formal evaluation of engineer knowledge and skills; implement a staff qualifications journal; verify field engineer education, certifications and previous employers; and ensure that formal performance reviews occur.

RPS Staff Training

Radiological Emergency Response Operations (RERO) Course

Hillary briefed RAC on a couple of specialized radiation emergency response trainings that staff attended in 2019. The first was a Radiological Emergency Response Operations (RERO) course offered by FEMA, in partnership with Department of Homeland Security (DHS), to train first responders, state law enforcements and emergency workers. RERO training offered helpful hands-on field response experience, including familiarization with different types of radiation detectors.

The sequel training is an Advanced Radiological Incident Operations (ARIO) course she also attended. It is designed for personnel managing a radiation incident from an Emergency Operations Center. The curriculum is being revamped to make it more educational.

Modular Emergency Response Radiological Transportation Training (MERRTT)

Rick highlighted the MERRTT course that RPS Emergency Response Team (ERT) staff attended. It was a 2-day training sponsored by US Department of Energy, waste isolation pilot project (WIPP) on radiation waste transport emergency response. Among the 16 course modules were sessions on radiological basics, biological effects, hazard recognition, patient handling, transportation of safeguards material, and transportation of radiation waste by rail.

RPS staff participated in other 2019 trainings including, US Naval Propulsion Team Training; NRC Environmental Monitoring, Air Sampling, Material Safety, Inspections, and Licensing courses; Drones for emergency response; Monthly ERT trainings; and Incident Management Team.

Rick also reported that 4 RPS staff were asked to be part the of Oregon Health Authority, Public Health Division “Incident Management Team” with a commitment for on-going monthly training and drills.

2020 RPS Priorities

David shared 2020 RPS priorities:

- Prepare a 2021 Legislative Concept for fee increases and prepare for the Oregon Legislature process, including stakeholder engagement plan.
- Fill the vacant AS1 Position.
- Decrease the backlog of inspections.
- Operationalize the RML Web-based Licensing and Inspection Databases

BREAK

Exemptions/Rules/Statutes

VCA NW Veterinary Specialists – Operation of Linear Accelerator

Rick introduced VCA representatives who were at the RAC meeting to present an exemption request allowing their Certified Veterinary Technicians (CVTs) to be operators of their linear accelerator machines, under the supervision of a veterinary radiologist. He noted that, for the past few years, RPS has granted VCA exemptions that allows their Certified Veterinary Technicians (CVT's) to assist the veterinarians (as operators) when they use the fluoroscope and computer tomography (CT).

The representatives explained that after a change ending the grandfathering of CVT's to take the national ARRT fluoroscopy exam, it became harder to hire CVTs. There is no difference between fluoroscopy machines (and operator training) used for human, versus animal patients. Because of this, VCA said their CVT's can make significant increased wages working in a hospital and are leaving their veterinary practice. Presenters expressed how instrumental a role CVT's have played in assisting their veterinarians to use fluoroscopy and CT.

The representatives reported that Oregon is experiencing a shortage of certified veterinary technicians (CVT's) who receive formalized radiation use and safety as a part of their formal education, and that their clinics need VA's to ensure the veterinarians can deliver services to their patients (animals) by operating CT and fluorography.

VCA representatives shared that most of their veterinary technician assistants have completed radiation safety training and that, as operators of CT and fluoroscopy, they would be supervised by a veterinary radiologist. David Howe asked for clarification on what type of "supervision" (personal or direct) would be provided. The presenter indicated that, like CVT's, personal (in the room) supervision would be provided for fluoroscopy, but for CT it would depend upon the radiologist.

Barbara Smith inquired about what kind of formalized education their vet assistants receive. VCA said VA's do not receive any formalized academic education. They are only required to have 2 years of hands-on veterinary practice experience to qualify as a vet tech assistant. Their basic radiation knowledge comes from working in the veterinary practice setting.

Todd Carpenter pointed out that the requested exemption is impacted by comprehensive OAR's dealing with operator and supervision requirements which should be properly vetted. Donna Stevens added that Wagner and Archer.com has fluoroscopy education/training requirements for Oregon physicians.

Note: VCA is interested in having their vet tech assistants serve as CT and fluoroscopy operators.

They are not suggesting this is on behalf of all vet tech assistants in the state.

David reinforced that even though RPS appreciates the VCA challenge to recruit and retain CVT's, it is not guided by business practice issues. The primary RPS charge is to ensure that radiation use and safety standards are maintained for the protection of operators, patients and the public.

Barbara requested that RPS further explore the training issues related to vet tech assistants being involved with CT and fluoroscopy. VCA said they would forward additional vet tech assistant training information to RPS for further consideration.

Donna asked if the RAC was ready to make a motion to recommend that RPS consider the VCA exemption request to allow vet tech assistants to assist in fluoroscopy and CT procedures.

Motion

Barbara Smith subsequently moved, and Fred Bremner seconded her motion to table this topic until the June 10, 2020 RAC meeting.

Advanced Practice Registered Nurse's (APRN) Fluoroscopy Supervision

Update

David Howe gave an update on Senate Bill 128 which permits APRN's to supervise registered radiological technologists during fluoroscopic procedures. Since January 27th, 2020 when the bill became law, the Oregon Board of Medical Imaging (OBMI) has established permanent rules. OBMI has already received three waiver requests to clinical requirements. Based upon provided documentation, two waivers have been granted. OBMI anticipates that there will be very few APRNs who meet the training and education, or waiver requirements, to supervise fluoroscopy procedures with a registered radiologic technician working as the machine operator.

Dexcowin Handheld Dental X-Ray/1.7 mA Exemption Request

Originally, Dexcowin requested to sell its hand-held dental X-ray device in Oregon. However, due to it having 1.7 mA (versus OAR required 2.0 mA), RPS denied the request. Dexcowin subsequently requested an exemption to the rule.

Rick researched the safety issues of machines with 1.7 mA, versus 2.0 mA, and did not find any concerns. Barbara suggested RPS look into whether other states permit and that RPS could then put a range of acceptable mA into permanent rule. Rick shared that he had actually surveyed other states and found that many have accepted 1.7 mA devices. He asked if RAC would consider making a recommendation to grant Dexcowin an exemption allowing the 1.7 mA hand-held device to be sold and used in Oregon. Rick added that RPS will most likely see other vendors make the same request.

A RAC motion was then made to recommend granting the Dexcowin exemption to allow their 1.7 mA Handheld device for sale in Oregon.

Motion

Fred Bremner moved, and Melinda Krahenbuhl seconded the motion to recommend approving the exemption. The motion carried unanimously.

Dexcowin ADX6000 Handheld Medical X-Ray Device Exemption Request

Rick reported that Dexcowin also submitted an exemption request for a hand-held medical X-ray device (Dexcowin ADX6000). Because the ADX6000 design did not comply with RPS's Oregon Administrative Rules (OAR) in not having a permanently affixed backscatter shield, the exemption request was denied. Dexcowin then modified the device which is now in compliance with OAR specifications. The manufacturer would like to use this device for dental use, as well as to image other body parts such as orthopedics.

Rick shared that Dr. David Hamby, a faculty member of the School of Nuclear Science and Engineering at Oregon State University, has done a study on the ADX6000 device which indicates it is acceptable for use on all body parts, not just as an oral imaging device. Of note is that the study only shows pictures of an alpaca's skull and no other human body parts.

Donna Stevens had a concern that the ADX6000 is a hand-held device and there appears to be no means to prevent the focal spot from **drifting or moving** during exposure of larger body parts.

Barbara Smith asked who would be allowed to operate this device. Even a dental setting, trained staff are the operators. She feels further investigation will be necessary before RAC is in a position to make a recommendation.

Fred Bremner shared that while working at free dental clinics, he has observed violations relating to how and where X-ray machines are set up (distance issues) which lead to possible unnecessary exposures.

Donna observed that current Oregon regulations do not permit using the ADX6000 handheld device for imaging full-size body parts.

RAC members felt that the exemption request wording does not address basic radiation safety and body imaging protocol concerns.

Motion

Barbara Smith moved to recommend denying the exemption request, and Fred Bremner seconded the motion. The motion carried unanimously.

Kaiser Cardiovascular Tech Training Exemption (handout available) *

Rick reported that Kaiser Permanente (KP) has contacted RPS to be granted an exemption to allow their cardiovascular technicians to act as operators by moving the table, if they have received in-house training. KP has also requested this to be a permanent rule. In the meantime, they are asking for a second RPS extension to an original exemption of providing RPS with information relating to reporting any adverse effects of CVT's moving the table.

Motion

Barbara Smith moved, and Fred Bremner seconded a motion, for RAC to recommend extending the exemption through the end of October 2020, to allow a review of KP's information by RAC during the June RAC meeting. The motion carried unanimously.

Gonadal Shielding Requirement Repeal(handouts)

Rick reported that, based upon an American Association of Physicists in Medicine (AAPM) study/position statement and prior RAC discussion, RPS decided to repeal the requirement for gonadal shielding.

Work Lunch

Senate Bill 283 – Wireless Technology Information Distribution

David gave an update on Senate Bill (SB) 283 which was enacted during the 2019 legislative session. The Bill requires the Oregon Health Authority to complete a review of peer reviewed, independently funded scientific studies on the health effects of exposure to wireless technology radiation in school settings. Hillary Haskins has been heavily involved in the preparation process, including identifying and recruiting two Oregon State University graduate students to serve as researchers and being assigned as one of two coordinators (with Dr. Ali Hamade) to facilitate the project. The research is slated to be done Spring to early Summer terms.

HB 4041- HB 4042 - SB 1508

David provided 2020 Legislative Bill briefings.

HB 4041 is a proposal to create, among other things, a department of emergency management, versus office of emergency management, and to form the Office of Fire Marshall into its own agency.

HB 4042 establishes training requirements for individuals who assist professional first responders in short-term emergency and recovery events.

SB 1508 creates a database of community emergency response team members and defines an “emergency response team” as a group of volunteers who are trained in accordance with guidelines adopted by the Federal Emergency Management Agency (FEMA) which provides emergency services in a community, neighborhood or locality.

Proposed Rulemaking – Todd Carpenter **Rule Packet 1 Industrial Rules (Refer to Handout) ***

RPS is proposing to centralize all rules relating to Radiation Generating Devices (RGD) into one division within chapter 333 to provide better clarity to licensees about their regulatory responsibilities.

RPS also proposes to amend rules within division 100 to repeal the requirement that radiation cannot be used for screening or inspecting and corrects the inspection frequency of dental registrants from every three years to four years.

As a part of proposed rulemaking, Todd presented RAC with the fiscal impact statement and requested their approval.

Motion

Barbara Smith moved, and Fred Bremner seconded that RAC accept the fiscal impact statement and for RPS to hold off on repealing the use of radiation for screening purposes until further discussion at the June 2020 RAC meeting. The motion carried unanimously.

Rule Packet 2 Admin. Changes & Permission for Dermatologists to Supervise Superficial Electronic Brachytherapy (Refer to Handout) *

RPS is proposing rule making within chapter 333, divisions 101, 102, and 123 pertaining to RPS's X-ray regulatory program.

Proposed rulemaking for the X-ray program would allow: a practitioner of the healing arts to use a superficial electronic brachytherapy (SEB) device; not allow the transfer of a X-ray machine registration to another person; discontinue slice thickness measurement testing with computed tomography X-ray systems; discontinue the requirement of a dental registrant to conduct radiation surveys; discontinue the requirement that a registrant must utilize a radiation safety committee to review results of the fluoroscopic Quality Assurance program; and remove the option of allowing practitioner direct supervision (only permit personal supervision) during the activation of fluoroscopic X-ray tube.

Motion I

Fred Bremner moved, and Barbara Smith seconded a motion to accept the Statement of Need and Fiscal Impact as read. The motion carried unanimously.

Motion II

Fred Bremner also moved, and Barbara Smith seconded a motion for RAC to accept the rules as read. The motion carried unanimously.

2021-2023 Legislative Concept Proposal RPS Fee Increases * (Handouts)

David reported on critical RPS issues, including:

- RPS has a growing expenditure, versus revenue gap.
- There is a need to create new funding.
- Without additional funding, a reduction in staff and services will be required
- There is a 676 Inspection backlog.
- Additional inspectors are needed to address the backlog.

David pointed out that, historically, RPS fees have been significantly low compared to other states, and even lower when compared with the Nuclear Regulatory Commission's (NRC) fee schedule. When combined with the growing funding gap, it is reasonable to propose an increase in user-fees.

Increased funding would allow RPS to: continue effective regulation of registrants and licensees; evaluate the use of emerging technologies; and support the state's triple aim effort of improving health, providing better healthcare and lowering costs.

David introduced the idea of implementing a progressive six-level, X-ray tube fee schedule based upon tube type and energy level; initiating an annual X-ray vendor license fee; instituting an annual Tanning registrant user-fee increase; and implementing two different RML user-fee increases depending upon a licensee's current fee level.

The proposed funding mechanisms have been forwarded to OHA senior leadership for their support and approval. If enacted, new funding will eliminate a projected, growing deficit and leave an adequate starting balance for the 2023-2025 biennium. David asked for RAC's support of the proposed new funding strategy.

Motion II

Barbara Smith moved, and Fred Bremner seconded a motion, that RAC supports RPS to pursue the four presented funding mechanisms as a means to increase needed program funding. The motion carried unanimously.

Emergency Preparedness/Response

Rick reported on upcoming RPS training, including: a CGS Hanford Dress Rehearsal Exercise Feb. 25th, 2020; the full CGS Hanford Exercise March 23rd & 24th, 2020; and RAD Responder Training Feb 19th & 20th, 2020. An update on development of the Radiation Drone Fleet was also given.

Miscellaneous – Mandatory RAC Member Training

David shared that the State of Oregon has implemented a new requirement that all members of agency boards, commissions, committees, plus state employees, must complete mandatory on-line trainings covering sexual harassment, discrimination

and workplace safety. More information about how to access the training, via the state's I-Learn system, will be forthcoming.

Open RAC Member Comment

Dr. Cyman expressed a strong concern about the VCA exemption proposal; that she believes there are significant operator safety and patient treatment issues related to Vet Tech Assistant not having adequate education and training (high school education only) to be operators of CT and fluoro.

Regarding CVT's operating linear accelerator, she used the example that for her it is challenging to keep up with the technology even for someone with her extensive and specialized training. (Medicine requires 10-14 years of training before becoming a fully-fledged practitioner).

Adjournment

The meeting adjourned at 2:19 p.m.

The next meeting for the Radiation Advisory Committee is scheduled for June 10, 2020.

Respectfully,

Lee Lind