RADIATION ADVISORY COMMITTEE MEETING Minutes October 11, 2017

<u>Call to Order – Public Session</u>

Donna Stevens, Chair, called the Radiation Advisory Committee (RAC) into public session on October 11, 2017 at 10:05 a.m. in Conference Room 1E of the Portland State Office Building.

Members Present

Stevens, Donna (Chair)
Bremner, DMD, Fred
Franco, Janet
Henrikson, Mandy
Smith, Barbara
Reese, Steve, PhD
Young, Scott

Members Absent

Cyman, DVM, Juliana

OHA Representatives

Howe, David Carpenter, Todd Wendt, Rick Villamar, Glenda Eric Packard Riven Leigh, RPS/OIS Lind, Lee

Guests

Ourso, André, Administrator, JD, MPH Luke Breazeal - OR Imaging Center Conlow, Executive Director, Ed Fishman, Kal - Sensus Cornish, Megan - Sensus Sardano, Michael - Sensus

Introduction of Members and Guests

Radiation Advisory Committee members, Radiation Protection Services (RPS) personnel and guests introduced themselves. David Howe welcomed representatives from Sensus Healthcare.

Approval of Minutes

Minutes from the June 14, 2017 meeting were sent to the members for their review, prior to this meeting. The June 14, 2017 Radiation Advisory Committee minutes were approved unanimously.

RAC Membership and Bylaw Review

David explained the RAC membership process. Every year, terms expire for two positions. RAC bylaws allow a member to serve 2 full terms. Barbara Smith and Donna Stevens terms are expiring, effective December 31, 2017. However, both are eligible for reappointment and RAC approved same at the June 7th meeting. Since then, André Ourso, our new Center Administrator, has forwarded their names as candidates for reappointment to the Director of OHA. Upon approval, Ms. Smith and Stevens should receive reappointment letters within 4-6 weeks.

Meeting Structure/Review Agenda

Donna announced there have been two topics (Travel Approvals and ODOT-Special Permits) added to the meeting agenda.

Donna suggested an option of having a time keeper for the future meetings, in order to cover the listed agenda items After a brief discussion, RAC members came to a consensus that time should be kept by the Chair, considering she/he would have a better understanding of the agenda items. The chairperson will meet with David prior to the meeting to go over agenda topics.

Donna also asked about/discussed when upcoming RAC meeting materials should be distributed to the members. After a brief discussion, it was decided a meeting packet should be mailed out to RAC members no less than a minimum of 10 days prior to the meeting. Informational items vs. action items are to be flagged.

Program Update

David shared the Section Mapping Project. RPS was the first section to go through the process. Graphically, the mapping shows RPS to be a small section compared to other PHD sections, and yet, it shows the varied functions/complex nature of the program. The RPS Section Map also identifies the statutes and rules which guide the section, and shows how RPS fits into the Public Health Division. It further reflects RPS is a user-fee based program, and shows the number of inspections, registrations and licensing actions completed. Lastly, it indicates actual vs. authorized FTE's. The map identifies that RPS needs additional funding/FTE to meet an increasing work load. Based upon preliminary budget forecasting, David will propose to PHD Senior Leadership that there is funding to support hiring 2

additional inspection FTE's as a part of the RPS Strategic Plan for the 2019-2021 biennium.

RPS Budget

David shared that RPS management is beginning a 2019 Strategic Planning Process. A meeting between members of the Public Health Director's office and selected RPS management and staff was held on September 11, 2017. One of the RPS priorities is reintroduction of a Legislative Concept to develop a Laser Regulatory Program. Since there is an unknown number of Lasers in the State (the number of potential Registrants), it would be a challenge to create a user-fee funding strategy. Creation of a Laser program would require Senior PHD leadership, Governor's Office and Legislature support/approval, and new administrative rules. RPS already has draft rules created with a focus on operator training/education and safety.

Another RPS priority is the need to enhance program funding through increasing existing/creating new user-fees (e.g. license amendments, incident mitigation/recovery fees, etc.) The last time RPS increased fees was 2015. It is possible that any PHD approved RPS user-fees will be integrated into the PHD's "Agency Request Budget" to the Legislature for the 2019-2021 biennium.

Electronic Products Update

Glenda Villamar reported on development of a new database system. Riven Leigh from the Office of Information Services (OIS) has been working on the new database. Once the system is on line, it will allow registrants to pay registration renewal fees and download their validation certificates. It will ultimately allow RPS inspectors in the field to input real time inspection data directly into the database. The overall goal is to have all RPS programs connected to a web-based database.

Glenda shared that on October 2, 2017 a fluoroscopy sub-committee met to discuss potential OAR revisions in regard badging staff working in OR suites which use fluoroscopic equipment.

Barbara Smith will be added to the Fluoroscopy Sub-committee.

X-Ray

Glenda said Inspectors have noticed that there are a lot of new imaging managers in medical facilities around the state. Most of these new managers are experiencing their first RPS facility inspection and do not know what to expect or how to locate requested records.

There is a growing RPS concern that vet assistants are being used to assist in x-ray exams. Current RPS OAR's only require basic radiation safety training for vet technicians (not vet assistants). RPS may need to address this matter for vet assistants.

Glenda pointed out that it there is a responsibility of registrants to inform RPS of any X-ray/tanning equipment changes and to update their device information. However, RPS is finding that many registrants are not updating their machine information as required.

Glenda reported that RPS Administrative Assistant Nic Riley is currently working on a new process to track the status of all issued civil penalties. When completed it will allow all RML X-ray and tanning civil penalties/final orders to be tracked and maintained by one person.

Tanning

David provided a status update regarding the on-going civil penalty process for Lioness Holdings-Tan Republic relating to non-payment of 2016 and 2017 registration fees for 20 facilities. After proving its case at an administrative hearing, OHA/RPS issued a final order that requires payment of \$20,550 for 2016 registration fees and to pay \$269,205 in civil penalties for failing to pay its 2016 registration fees. Because RPS has not received any registration fee payments for 2017, our agency has also begun processing "notices to impose" civil penalties for non-payment of Lioness Holdings 2017 registration fees. If the company does not pay, RPS is considering to file a complaint for injunctive relief. The filing would be with a court asking that Lioness Holdings cease operations at its 20 Tan Republic facilities unless or until the company comes current with its 2016/2017 registration fees and pays the \$269,205 civil penalty.

IMPEP

David shared up-to-date results of the August 7-11, 2017 IMPEP audit. The audit team focused on 5 performance indicators including Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Inspection, Compatibility Requirements and Technical Quality of Licensing Actions, and Technical Quality of Incidents and Allegations.

The Draft IMPEP Report shows that RPS received "Satisfactory" ratings for each performance indicator, and an overall program "Adequate and Compatible" finding, which are the highest possible ratings/finding possible. There was one recommendation related to correcting a "program code" which is being dealt with by Licensing Manager Todd Carpenter and RML staff.

RPS has been invited to submit a written response to the draft IMPEP report for the NRC Management Review Board's (MRB's) consideration. David will attend the MRB meeting, October 26, 2017 in Rockville MD, where the report findings will be finalized.

Staff Training:

Rick reported on recent and upcoming RPS staff training events.

Travel Approvals

David spoke about recently instituted travel restrictions as a result of state budget concerns. All travel, beyond routine trips between Portland and Salem, now require Agency Director Office approval. Because the nature of RPS job responsibilities are to meet compliance or regulatory requirements, David has submitted a request for a "blanket travel approval" for all in-state regulatory trips.

Proposed Rulemaking

Todd Carpenter reported on Federal Rule Compatibility Revisions which have been filed and accepted by the Secretary of the State. He said that RPS received 3 comments prior to the filing of the rule packet. All three comments were about CT operator requirements.

OBN Proposal (CRNA's Doing Fluoroscopy)

David gave an update regarding an Oregon State Board of Nursing (OSBN) proposal to allow CRNA's to supervise interventional pain management fluoroscopic procedures for needle placements-an activity currently prohibited in Oregon. A rule advisory committee tried to address an OAR language conflict pertaining to the definitions/roles of "operator" versus "supervisor", and the working relationship between the CRNA and licensed radiological technologist teaming up for the mentioned medical procedure.

David attended a meeting with Oregon Board of Medical Imaging (OBMI) and the OSBN Executive Directors and their legal Counsel to discuss the role of the CRNA interacting with a licensed radiological technologist. A new OBMI statute would be needed and RPS would institute new OAR's to address CRNA qualifications, as well as specific didactic, applications and clinical radiation use and safety training requirements. Please refer the handout.

Since proposed RPS rules have already been presented to RAC, David asked if RAC could provide a recommendation from the information provided because OBMI will be addressing this matter in less than 2 weeks at their OBMI meeting. They intend to discuss/possibly approve proposed statutory language. Assuming there is future OBMI/legislative approval for a new statute, RPS proposed qualification and training rules would be implemented as a part of a new statute.

Motion

Dr. Fred Bremer moved and Barbara Smith seconded a recommendation motion to approve going forward with rule making. The motion passed unanimously.

RPS Web Database

Riven Leigh provided a live demonstration of our RPS X-ray website customization. Once completed, the inspectors will be able to access real time facility information, electronic inspection forms and do inventory reconciliations while in the field.

Health Division Updates

The new Administrator for Center for Health Protection, André Ourso, MPH, attended the RAC meeting for the first time. André shared that he has a broad public health background. He has a law degree and practiced for a short time in

Florida. He then held the position of Executive Director for the Florida Board of Medicine. He also worked briefly with the Florida Radiation Protection Section as well. André said that he has a broad view of public health and views everything through a public health and legal lens. He welcomed questions and comments.

André also shared that the Public Health Division has Three Administrators, who report to the Public Health Director. Recently, Patrick Allen was appointed by the Governor as the new OHA Director. Mr. Allen came from the Dept. of Consumer Business Services. He has been a career public servant for past 25 years. André has found Director Allen to be very personable, engaged, and someone who makes himself accessible. Overall, Director Allen has a strong public health and regulatory background.

Lunch Break

SENSUS Healthcare Superficial Radiation Therapy (SRT-100) Device Presentation

[Note: In August 2017, Sensus Healthcare, manufacturer of an electronic brachytherapy device, approached RPS about granting a possible variance/rule revision to allow dermatologists to operate/supervise the use of their superficial radiation therapy device (SRT-100) in Oregon. At the time of the variance request, RPS was already conducting a preliminary study regarding OAR device, operator/supervisor qualification and training requirements. Current OARs do not allow dermatologists to use the SRT-100 device (only radiologists, radiation oncologists, and radiation therapists are permitted to do so). Because RPS staff use the Radiation Advisory Committee (RAC) to vet variance/rule revision proposals, RPS invited Sensus to make a presentation to RAC at the next available Oct. 11th 2017 meeting.]

RAC meeting Sensus representatives included Kal Fishman, (Chief Technology Officer), Michael Sardano (Legal Counsel), and Megan Cornish (Outside Business Consultant). Mr. Fishman gave the SRT-100 presentation (Handouts provided). He covered the history of Sensus Healthcare including current use/access by 38 states, plus device benefits, versus more invasive skin cancer surgical procedures (e.g. Mohs) and unique features of the device. He also spoke about how the device is sold/serviced (company help line available for users) and presented the applications training program.

RAC members asked questions about DO/MD training, the length of training, device dosage levels, length/number of fractions, patient positioning aids, and resiliency of the x-ray tube.

Immediately following the presentation, RAC members requested that RPS forward the Sensus SRT-100 applications training materials to them for further review/consideration before making any variance/rule revision recommendations. RPS staff will send the materials.

It was moved and seconded that RPS form a sub-committee to complete more indepth evaluation and make recommendations relating to OAR device, operator qualification and training issues pertaining to dermatologists using the SRT-100 device. The intent is for RAC members to review/take action on the sub-committee evaluation/recommendations at the Feb. 14, 2018 RAC meeting.

There was unanimous motion consensus.

Emergency Preparedness/Response

Rick Wendt reported on an upcoming dress rehearsal in February 2018 for a Columbia Generating Station/FEMA Exercise. The full, evaluated drill will take place in March 2018.

Rick told/showed the RAC about newly acquired radiological emergency response equipment, purchased with a Health Security Preparedness and Response (HSPR) grant. The new equipment includes two portal monitors, five kits containing different digital radiation detectors, two portable gas generators, and lap top field computers. The equipment will be used in support of creating "community collection centers" for mass population contamination screening and RPS field team responses in the event of radioactive material releases. RPS intends to provide equipment training to community volunteers.

Radioactive Materials Processing

RPS Environmental Health Specialist (EHS) Eric Packard reported on a recent RPS project to dispose of low level radioactive material (RAM) waste. On July 30th, 2017 Eric lead a disposal team consisting of RPS team members Hillary Haskins, Glenda Villamar and Manager Todd Carpenter, to identify, classify and properly repackage RAM waste for disposal. RPS partnered with METRO South by using their Hazardous Materials facility.

RPS-DEQ Interagency Agreement (IAA)

Rick provided a briefing about a new Interagency Agreement (IAA) between RPS and DEQ in support of the DEQ "School Lab Clean Out" Program to assist in the removal and disposal of radioactive materials from high school labs. In the past, RPS provided this service at no charge to DEQ. However, to address RPS funding/staffing restrictions, DEQ School Lab Clean Out Program grant monies will be used to reimburse RPS for processing/disposing these radioactive materials. Based upon DEQ referrals, RPS will make arrangement with schools to identify, characterize and dispose of radioactive materials on a billable hourly basis.

Meeting was adjourned at 2:05 p.m.

[Note: The next Radiation Advisory Meeting is scheduled for February 14, 2018 at 10:00 AM.]