



RADIATION ADVISORY COMMITTEE

BARBARA SMITH,
CHAIR

David Howe, Radiation Protection Services
Program Director

October 12, 2022



- Record phone-in number and passcode (in case you lose connectivity)
- Phone-in number and conference ID# provided in Teams invitation mail
- If phoning into meeting, use PowerPoint slides to follow meeting
- To unmute self, press *6



- Video (of yourself) is optional
- Please mute microphone unless speaking
- Use the “raise hand” feature if you have a question



- When speaking, begin by stating your name
- RPS staff will use screen share to share PowerPoint information and handouts
- The meeting will be recorded for purposes of accuracy in the minutes

TELECONFERENCING PROCEDURES

RADIATION ADVISORY COMMITTEE MEETING AGENDA

October 12, 2022 – Hybrid Virtual Meeting

800 NE Oregon St., Room 368, Portland, Oregon

Phone-In Number 1 971-277-2343 Code: 401 511 857#

(* = Action Items)

10:00 a.m.

Registration/Public Session

- Call Meeting to Order – Barb Smith, Chair
- Introduction of Guests
- Approval of Minutes – Barb Smith*
- RPS Staffing – David Howe (EHS3 - Rich Patterson & EHS3 - Sarah Brodesser)
- Nomination/submission of 2 RAC Members for 2023-2026 terms - *
Garrett Frey and Alicia Zambelli

10:30 a.m.

2022 RPS Program Updates – David Howe

- RPS Budget – Todd Carpenter, Licensing Manager, RPS
MQSA Contract Renewal
- Electronic / Tanning Products Update – Brent Herring, Lead Worker, RPS
- Radioactive Materials Licensing – Hillary Haskins, Operations Manager, and Todd Carpenter RPS
- Emergency Response / Incidents – Hillary Haskins
OHSU Tuality – NOV for physician overexposure
SkinCure Oncology & Central Oregon Dermatology – NOV for wrong treatment site
- RPS Training – Hillary Haskins

BREAK



11:15 a.m. Exemptions/Rules/Statutes

- OXOS Medical, Inc.- Micro C Medical Imaging System M01 Follow up questions - Susan Atkinson*
OAR Rules for exemptions
- Exemption request for Fujimi Corp. - Kanomax Model 3550 Annular Flow Ion Mobility Classifier for industrial use – Alex Fajardo *
OAR Rules for exemptions

Rulemaking

- Rulemaking Advisory Committee Meeting – Todd Carpenter *
Proposed radioactive material rulemaking within divisions 102, 105, 116, 118, 120, 121, and 125 are being drafted to be compatible with the Nuclear Regulatory Commission’s federal regulations. Drafts of the Notice of Proposed Rulemaking and the Statement of Need and Fiscal Impact forms.
- Proposed Oregon Board of Medical Imaging (OBMI) rule regarding extremity CT’s – Brent Herring*

11:45 a.m. Lunch

12:15 p.m. Emergency Preparedness/Response

- Puget Sound Naval Shipyard – Nuclear Core Compartment Inspection and tour – Hillary Haskins
- FEMA – Evaluated Dress Rehearsal Drill (9/13/2022) – Hillary Haskins
- ROSS – Radiation Operation Support Specialist – Hillary Haskins
- Ukraine Nuclear Power Plant Monitoring – David Howe


12:45 p.m. New Business

- 2023 hybrid RAC meetings – David Howe

1:30 p.m. PUBLIC COMMENTS:

2:00 p.m. Announcements \\ Next meeting scheduled for February 15, 2023 /Adjourn





**APPROVAL OF MINUTES FROM
JUNE 15, 2022**

Radiation Advisory Committee Meeting



RPS STAFFING

DAVID HOWE

- New Staff Hires
 - Rich Patterson – EHS3
 - Sarah Brodesser – EHS3
- RPS at full staffing

WE WELCOME RICH PATTERSON TO RPS!!



- Environmental Health Specialist 3 (EHS3)
- Crossed trained in performing tanning, x-ray and RML facility inspections plus radioanalytical laboratory and Emergency Response Team assignments
- Experience/Education
 - Over 14 years at three California County Environmental Health Departments as an Environmental Health Analyst performing hazardous waste/cannabis regulatory inspections
 - Food, soil and water laboratory analysis
 - BS Degree in Environmental Science from California State University and Masters in Public Health from St. Georges University

WE WELCOME SARAH BRODESSER TO RPS!!



- Environmental Health Specialist 3 (EHS3)
 - Crossed trained in performing tanning, x-ray and RML facility inspections plus radioanalytical laboratory and Emergency Response Team assignments
- Experience
 - Reed College research nuclear reactor where she served as an NRC-licensed nuclear reactor operator
 - Technologist at Molecular Testing Labs in the medical toxicology area
 - Contract Chemist for Hewlett Packard testing medical device prototypes and consulting with the engineering team.
- Education
 - Bachelor of Science degree in Biochemistry from Reed College.

Oregon Health Authority
Public Health Division
Radiation Protection Services

David Howe
Section Manager
Principle Executive/Manager F
0000310, X7010, PERM

ER/Technical Services/Field Operations

Preparedness/Licensing

Hillary Haskins
PEM-D/Job Rotation
Health Physicist
Environmental Health Specialist 3
0001171, C3819, PERM

Patricia Thompson
Administrative Assistant
Administrative Specialist 1
1002417, C0107, PERM

Todd Carpenter
Principle Executive/Manager D
0000681, X7006, PERM

Brent Herring
Lead Worker
Health Physicist
Environmental Health Specialist 3
0000157, C3819, PERM

Michelle Martin
Health Physicist
Environmental Health Specialist 3
1002811, C3819, PERM

Judith Smith
X-Ray Registration
Administrative Specialist 1
0000300, C0107, PERM

Erin DeSemp
Health Physicist
Environmental Health Specialist 3
0000464, C3819, PERM

Rama Wusirika
Health Physicist
Environmental Health Specialist 3
0000308, C3819, PERM

Toby Irving
Health Physicist
Environmental Health Specialist 3
0000392, C3819, PERM

Lee Lind
RML Registration
Administrative Specialist 1
0000706, C0107, PERM

Daryl Leon
Health Physicist
Environmental Health Specialist 3
0001170, C3819, PERM

Dong Lim
Health Physicist
Environmental Health Specialist 3
1018732, C3819, PERM

Richard Patterson
Health Physicist
Environmental Health Specialist 3
1019657, C3819, PERM

Alexandra Parker
Tanning Registration
Administrative Specialist 1
0000446, C0107, PERM

Thomas Pfahler
Health Physicist
Environmental Health Specialist 3
0000707, C3819, PERM

Sarah Brodesser
Health Physicist
Environmental Health Specialist 3
1018732, C3819, PERM

Thomas Mynes
Health Physicist
Environmental Health Specialist 3
0000387, C3819, PERM

Updated October 2022



NOMINATION OF (2) RAC MEMBERS FOR 2023-2026 TERM

Barbara Smith, Chair

RADIATION ADVISORY COMMITTEE MEMBERSHIP

Name	*First Term	Second Term	Third Term	Comments
Frankel, Jennifer	01/01/21-12/31/24			
Cyman, Juliana	01/01/15-12/31/18	01/01/19-12/31/22		
Berry, Bob	01/01/20-12/31/23			
Henrikson, Mandy	01/01/17-12/31/20	01/01/21-12/31/24		Vice Chair- 2nd term 01/01/21-12/31/22
Hamby, David	05/07/20-12/31/23 Replaced M. Krahenbuhl			
Smith, Barbara	07/25/14-12/31/17 Replaced R. Farmer	01/01/18-12/31/21	01/01/22-12/31/25	Chairperson- 1 st term 01/01/21-12/31/22
Wood, Dennis	01/01/22-12/31/25			
Young, Scott	01/01/15-12/31/18	01/01/19-12/31/22		
Frey, Garrett				Nominee for 2023
Zambelli, Alicia				Nominee for 2023

*May be partial term due to replacing a member. Bylaws state a member can serve two full terms after the bylaws were adopted.

NEW RAC MEMBER NOMINEE CANDIDATES

Alicia Zambelli, DVM

- Cornelius & Murray Hill Veterinary Practices- Associate Veterinarian
- Dove Lewis Emergency Animal Hospital- Senior Staff Veterinarian
- Fernhill Veterinary Care- Co-Owner
- Portland Veterinary Medical Association- Past President

Garrett Frey

- National Institute for Occupational Safety and Health- OMSH General Engineer
- US Dept of Labor- Mine Safety & Health Administration- Inspector & Accident Investigator
- Knife River Corp NW- Safety Manager/RSO

A festive autumn-themed background. At the top, a wicker basket is filled with green grass and red maple leaves. To the right, a large sunflower with bright yellow petals is visible. In the foreground, several pumpkins are arranged on a wooden surface. One pumpkin is carved into a jack-o'-lantern with a black face and is topped with a black witch's hat with an orange band. Another pumpkin is partially visible below it. Scattered around the pumpkins are various autumn leaves in shades of red, orange, and yellow, along with a few chestnuts. A dark, semi-transparent horizontal band is overlaid across the center of the image, containing the text.

2022 RPS PROGRAM UPDATES



RPS BUDGET

Todd Carpenter, Licensing
Manager RPS

Fiscal Year 21-23
Transition to New
State Financial System
Financial Reports
Delayed



X-ray and Tanning Renewal
Projects Complete – Revenue
Received as Projected

Materials Licensing Program
On-Going Quarterly – Billing
Revenue Received as
Projected

MQSA CONTRACT RENEWAL

Todd Carpenter



- Inspection Update
 - New Inspector Sign-offs
 - Toby Irving is signed off to perform dental, veterinary, chiropractic, medical, and MQSA inspections
 - Dong Lim is signed off to perform dental and tanning inspections
 - Rich Patterson is signed off to perform dental inspections
 - Inspections performed since last meeting:
 - 159 X-ray Inspections (medical, dental, veterinary, therapy, and industrial)
 - 429 machines and 431 tubes
 - 21 MQSA Inspections
 - 25 Tanning Inspections
- MQSA Contract and Inspections
 - Contract period is May 2, 2021 to May 1, 2022.
 - Contract has been renewed

ELECTRONIC / TANNING INSPECTION UPDATE

Brent Herring,
Lead Worker, RPS



RML PROGRAM UPDATE

- 63 inspections completed
- 37 inspections left for the year
- 136 completed licensing actions
- 99 open licensing actions

Hillary Haskins,
Operations Manager, RPS



EMERGENCY RESPONSE / INCIDENTS

Hillary Haskins

INCIDENT – OHSU TUALITY

- Notice of Violation (NOV) for physician overexposure
 - February 2020 – physician received ~ 7 rem
 - October 2020 – physician received ~30 rem year-to-date
 - December 2020 – reported dose to physician and Authority
- Investigation by Mirion determined dose to be ~17 rem



INCIDENT – SKINCURE ONCOLOGY & CENTRAL OREGON DERMATOLOGY

- Notice of Violation for wrong treatment site
 - Central Oregon Dermatology in Bend, Oregon. The investigation occurred following a self-reported incident involving seven superficial electronic brachytherapy fractions to the wrong site on a patient using a Sensus SRT Vision 100.



- NRC
 - IMPEP evaluator – Brent Herring
 - Inspection Procedures – Dong Lim
 - Security – Tom Pfahler
 - Environmental Sampling – Michelle Martin
 - Nuclear Medicine and Gamma Knife & HDR – Ram Wusirika
- Upcoming
 - Oregon hosting Inspection Procedures
 - Washington potentially hosting Licensing Procedures
 - Oregon helping train new Washington inspectors



RPS TRAINING

Hillary Haskins



BREAK



EXEMPTIONS/RULES/STATUTES



OREGON ADMINISTRATIVE RULES FOR EXEMPTION



OXOS MEDICAL, INC.
MICRO C MEDICAL
IMAGINING SYSTEM M01
FOLLOW-UP QUESTIONS



OXOS Medical Micro C M01 Materials for
Department of Human Services and Oregon Health
Authority (DHSOHA) Radiation Advisory Committee (RAC)

Micro C M01

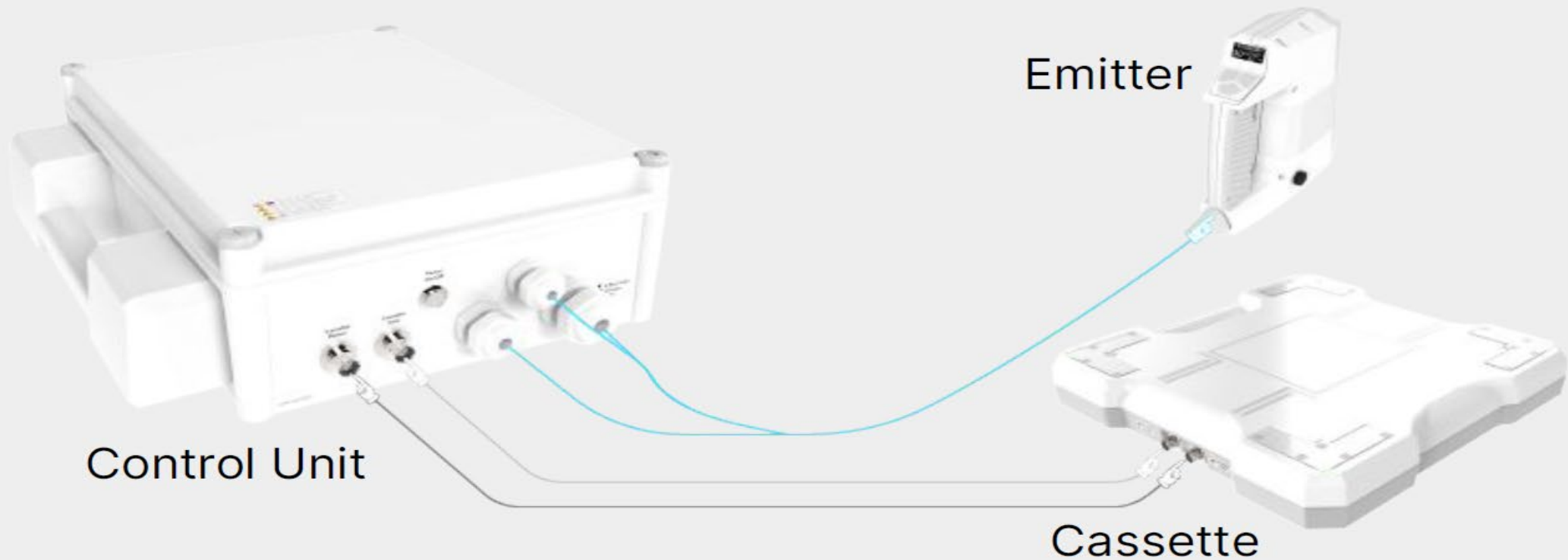
FDA 510(k) Cleared
([K203658](#), [K211473](#), [K212654](#))

Portable x-ray system under IZL
FDA product code. Micro C M01 is
a complete system, not disparate
x-ray source and x-ray detector;
i.e., they cannot be separated.



private and confidential

Micro C M01 Major Components



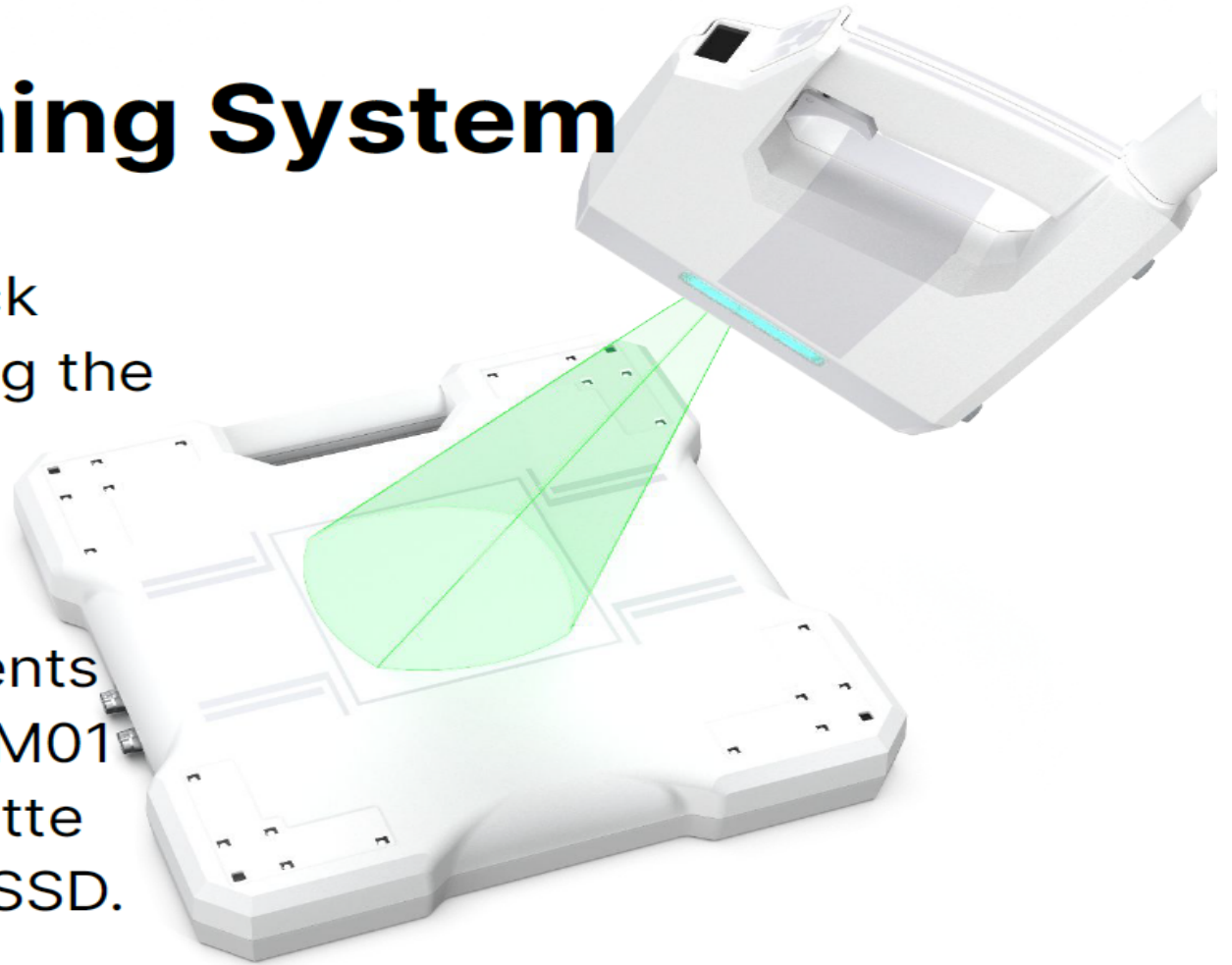
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OXOS

Safety & Positioning System

M01 Emitter and Cassette track each other in space, computing the absolute distance and offset between the two.

“No-Fire” Safety System prevents ANY emission of x-ray unless M01 Emitter is orthogonal to Cassette active area at proper SID and SSD.



Indications for Use

Micro C M01 is a portable general purpose X-ray system that is indicated for use by qualified/trained clinicians on adult and pediatric patients for taking diagnostic static and serial radiographic exposures of extremities.

The device is not intended to replace a radiographic system that has both variable tube current and voltages (kVp) in the range that may be required for full optimization of image quality and radiation exposure for different exam types.

Portable X-Ray Regulations



**Foot Pedal cord shown is not extended to its full 12-ft length, representation is only for photographic purposes

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Micro C M01 Meets all Portable Req.

- Micro C M01 meets all applicable sections of 333-106-0305, 333-106-0101.
 - Micro C M01 is not intended to be used in the same location for any extended period of time. Micro C M01 is meant to be a point-of-care imaging system, and it specifically permits the operator to be at least 12 ft from the tube housing assembly during exposure to meet 333-106-0305 (2)(b)(C)(ii).
 - Mechanical support of tube head is provided, per 333-106-0101 (9).

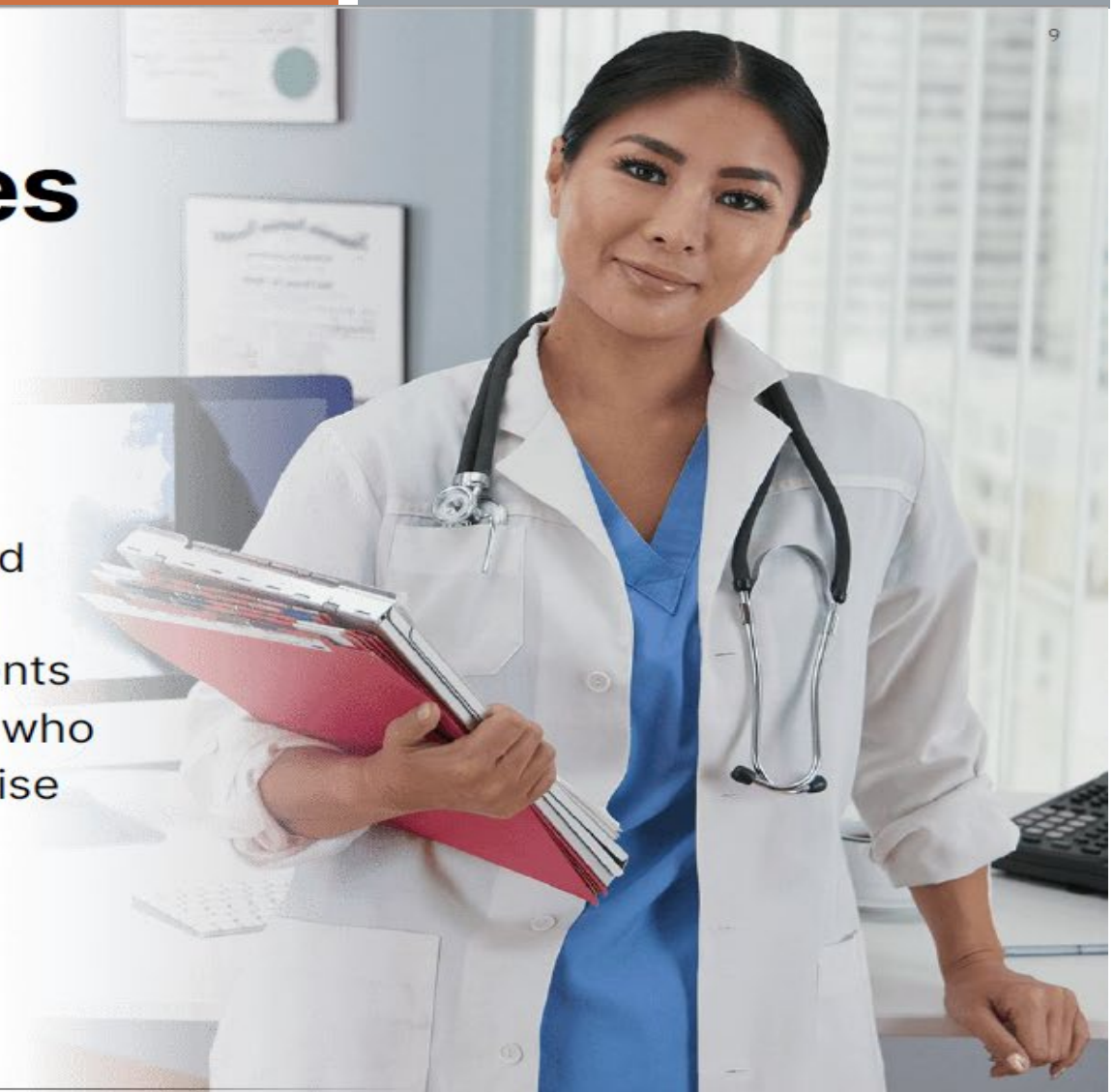
Micro C M01 Meets all Portable Req.

- 333-106-0310 (1-2): All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 cm.
- Operators are provided with a 30 cm ruler to ensure that the SSD requirement is met
- Customers are informed of state specific use requirements such as:
 - Operator and patient PPE
 - Locations for use (e.g. no hallways)

Potential Use Cases

Potential use cases of the Micro C M01:

- ASCs, Hospitals, Urgent Cares
- Mobile Providers/Suppliers for:
 - SNFs and Nursing Homes
 - Long-Term Care Facilities, Assisted Living Centers, Hospice Providers
 - Home Health to Homebound Patients (promotes health equity for those who are disabled, isolated, and otherwise do not have access to care)



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DDR

Dynamic Digital Radiography is a serial imaging modality that takes diagnostic quality, high-speed x-rays in quick succession.

Examples:

[Foot](#), [Knee](#), [Elbow](#), [Wrist](#), [Thumb](#)

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DDR vs. Fluoroscopy

- In its 510(k) clearance letter, the FDA did not assign any of the 6 potential fluoroscopy product codes to the Micro C; rather, it assigned product code IZL (Mobile X-Ray System), which is specified in 21 CFR §892.1720.
- The Micro C uses DDR (Dynamic Digital Radiography), a low-dose implementation of cineradiography, to produce a sequence of images that can be paused for single-frame viewing and diagnostic purposes.
- FDA explicitly requires OXOS to footnote all marketing materials to clarify that “DDR is not fluoroscopy.”

Rad. Physicist Approved

In addition to the FDA, third-party radiation physicist from Duke Health System has separately reviewed OXOS claims regarding Micro C M01 and summarized findings in [Expert Letter](#).

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Expert Letter
Medical Physicist Steven Mann, PhD, DABR
September 10th, 2021
Micro C Medical Imaging System, M01
Radiation Exposure & Safety

Forward

To Whom It May Concern:

I'm writing on behalf of OXOS Medical, Inc., for whom I serve as a 3rd party consultant medical physicist, to provide an objective review of the radiation exposure and safety characteristics of their current generation Micro C imaging device. Being an ABR board-certified medical physicist with extensive experience in fluoroscopy and radiography, I am well suited to the task of reviewing the qualities of this novel imaging system.

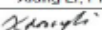
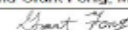
For organization, this letter is separated into two sections: Patient Radiation Safety and Operator Radiation Safety. Within both, I provide my objective opinion of the operational aspects of the Micro C device as it relates to each, including comparisons to existing and widely utilized technology.



Facility RSO Approved

Independent study performed by Rad. Safety Dept. at Cleveland Clinic validated leakage and scatter measurements and demonstrates Micro C M01 passes all facility safety criteria.

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RADIOGRAPHIC EQUIPMENT EVALUATION			
Site:	Fairview Hospital	Survey Date:	August 29, 2022
Department:	Orthopedics		
Room ID / Number:	Department Conference Room		
Medical Physics ID:	3755		
Clinical Engineering ID:	299265		
X-ray unit Manufacturer:	OXOS Medical, Inc	Detector:	MicroC, M01
Model:	MicroC, M01		
Dosimeter Base Unit:	Phys ID: 3000 RaySafe / X2 (8251010)	Serial:	296018
Accessory Equipment:	3001 X2 R/F Sensor (8252010-6)	Serial:	292201
Accessory Equipment:		Serial:	
Survey Type:	Demo Unit Acceptance Evaluation		
Performed by:	Xiang Li, PhD DABR CRE and Grant Fong, MS DABR DABMP CRE		
Signatures:	 		
Medical Physicist's QC Tests			
Visual Inspection		PASS/FAIL	Pass
Acquisition Workstation Monitor Check (optional)			n/a
HVL, kVp Accuracy, and Output Measurements			Pass
Exposure Reproducibility and Linearity			Pass
Timer Accuracy			Pass
Minimum Source-to-Surface Distance			Pass
Source-to-Image Distance Check			For Reference
Measured Field Size			Pass
Displayed Incident Air Kerma ($K_{a,i}$) Accuracy			Pass
Displayed Kerma Area Product (KAP) Accuracy			Pass
Patient Incident Air Kerma ($K_{a,p}$) Analysis - Single Radiographic Mode			Pass
Patient Incident Air Kerma ($K_{a,p}$) Analysis - Serial Radiographic Mode			For Reference
Spatial Resolution			For Reference
X-Ray Tube Leakage			Pass
Scatter Measurement			For Reference

OXOS



www.oxos.com
1230 Peachtree Street NE,
STE 300,
Atlanta, GA 30309

OXOSMEDICAL

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RPS FOLLOW-UP QUESTIONS TO OXOS

What is your exemption request: Handheld or Portable?

OXOS is seeking approval for use as a portable device. Does that require an exemption?

Leakage study for handheld – were values measured or estimated?

- Is it scatter radiation coming off the detecting device being shown on page 57?

Yes, that is correct – that shows the measured values. I have also attached an independent study performed by Cleveland Clinic if that is helpful.

If handheld, we would need to have an independent assessment of the device (requirement for handheld dental units).

Just portable at this time, but I have attached the independent assessments of the device which were previously submitted.

RPS FOLLOW-UP QUESTIONS TO OXOS

Is there one person or two working the machine? One working the machine and one moving the rest of the device? How is the patient limb being manipulated?

One person operating the machine using foot pedal. If the patient limb needs to be manipulated (other than by the patient), the operator is provided PPE (vest, gloves, etc.) in order to protect from stray radiation.

Where do you see this device being used? Mobile clinics, sporting events, etc.

Physician's offices at the point of care.

What's the scope of the machine? Are they using it for simple diagnostics or imaging?

It is used for simple diagnostics and is also indicated for use in surgery for simple imaging.

RPS FOLLOW-UP QUESTIONS TO OXOS

How is the receptor held during cross table?

There are accessories provided to the customer that hold both the emitter and the cassette to ensure that the operator should not need to hold any piece of the equipment in order to capture images.

How will source to skin distance be maintained? (OXO's machine minimum is 20 cm while our rule has a minimum of 30 cm.)

Federally, the OXOS device has been cleared at 20 cm, but in states that have the 30 cm rule (which is common), a ruler is provided in order to maintain state compliance.

We define fluoroscopy as a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. How does the device not meet this definition?

The provided OXOs definition is consistent with what RPS considers being fluoroscopy.

RPS OXOS EVALUATION – PROPOSED REQUIREMENTS

- **30 cm SSD with ruler demonstration**
- **In a surgical setting only; not used in hallways nor patient rooms**
- **Extremity use only**
- **Device is sold as a portable only.**
- **The stand is sold with the device. If the stand is not sold with the device then it is a hand-held which is not approved.**

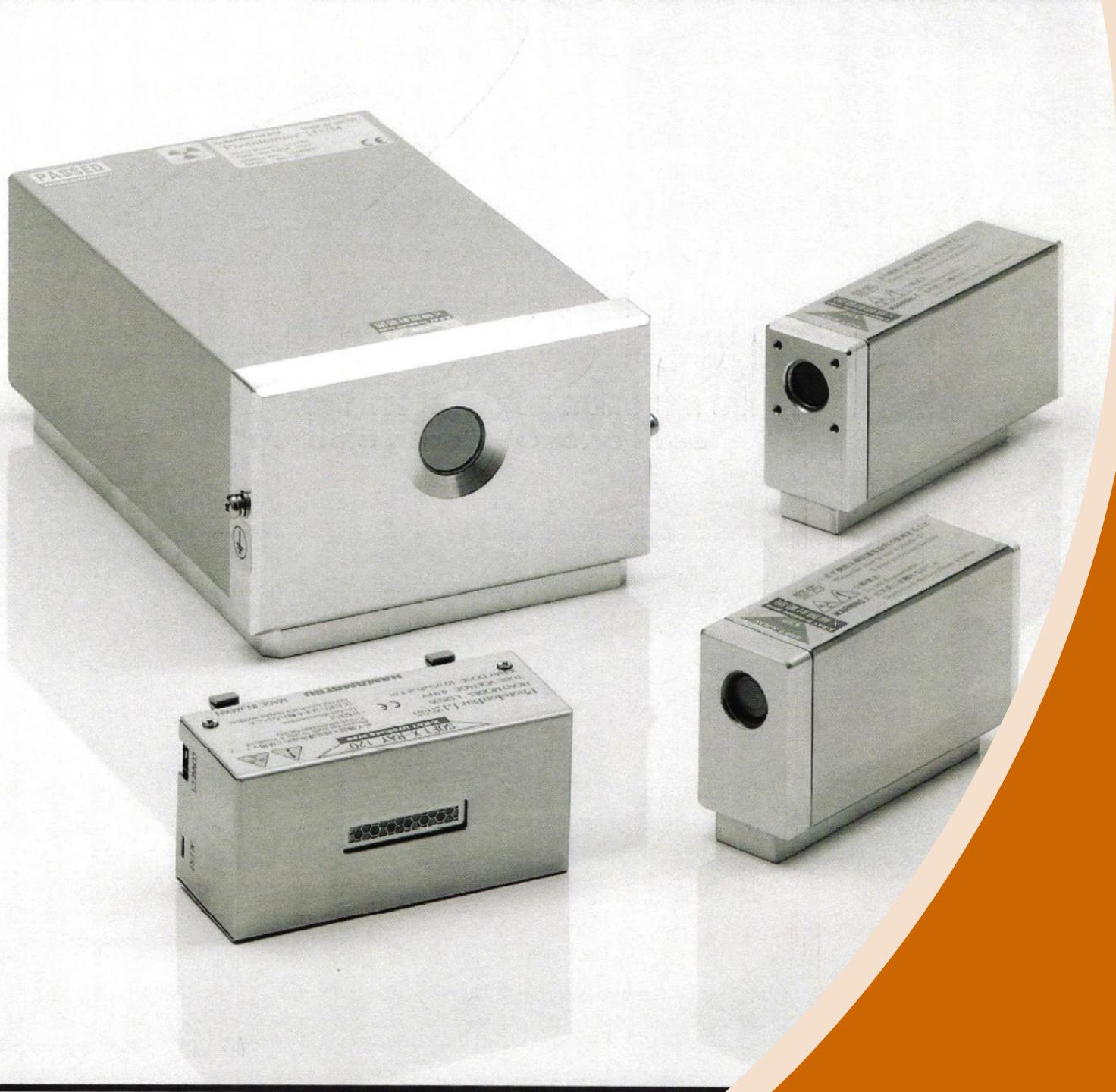
-
- **Applications training including use and set up with stand**
 - **Use equivalent rules Colorado stated in the approval letter for written procedures, over 7 consecutive day rule, under 7 consecutive day rule, etc.**
 - **Operators must follow RPS rules for fluoro supervision and operators**
 - **Make it clear who is allowed to do what with the machine and patient in terms of an operator**
 - **Need further clarification on the physics report.**



FUJIMI CORP. – KANOMAX MODEL 3550 ANNULAR FLOW ION MOBILITY CLASSIFIER FOR INDUSTRIAL USE

Fujimi Corporation Exemption Request

- Submitted documentation to request exemptions for OAR chapter 333, divisions 100 through 123 and 125.



Kanomax Model
3600 Annual Flow
Ion Mobility
Classifier

KANOMAX FMT, ON BEHALF OF FUJIMI CORPORATION, BELIEVES THE DEVICE MERITS AN EXEMPTION BECAUSE...

- The output radiation of the soft X-ray module (Hamamatsu Model L9873) has a peak wavelength of 0.2 nm with an energy between 3-9.5 keV, which is categorized as a Soft X-ray (lower energy compared to diagnostic x-ray).
- Soft X-Rays do not easily penetrate solid materials and are attenuated using relatively thin shielding.
 - The recommended thickness for stainless steel shielding for the model L9873 is 0.5mm.
 - For the charge conditioner housing used in the Model 3660 the minimum thickness of Stainless steel is 6 mm which is > 10x the minimum recommended.
- The user does not have access to direct radiation while using the instrument.
- The instrument includes a safety lockout and dual indicators for X-ray module power and active emission state.
- Fujimi believes that granting the exemption "will not result in an undue hazard to the public, worker health and safety, property or material security" per OHA OAR 333-100-0025.

RPS QUESTIONS & CONCERNS

- Most exemption requests are made for specific rules. This request is for all RPS Division rules, specifically, divisions 100 through 123 and 125.
- Is the intention to not register this x-ray device because of its characteristics?
- Are there requirements within Divisions 100-123 that create a burden for operation of this device?
- Does Fujimi want to be exempted from routine inspections?
- Other questions and concerns?

A scenic autumn forest with a stream and a large mossy tree. The ground is covered in fallen red and orange leaves. The stream flows through the center, reflecting the surrounding trees. A large, gnarled tree with thick, moss-covered roots stands prominently in the foreground on the left. The background is filled with tall, thin trees with vibrant autumn foliage.

RPS RULEMAKING

RULEMAKING ADVISORY COMMITTEE MEETING

TODD CARPENTER

- Proposed radioactive material rulemaking within divisions 102, 105, 116, 118, 120, 121, and 125 are being drafted to be compatible with the Nuclear Regulatory Commission's federal regulations. Drafts of the Notice of Proposed Rulemaking and the Statement of Need and Fiscal Impact forms.



NOTICE OF PROPOSED RULEMAKING WORKSHEET

For internal agency use only. Not a valid filing form.

Oregon Health Authority, Public Health Division		333
Agency and Division Name		Administrative Rules Chapter Number
Brittany Hall	800 NE Oregon St. Suite 930, Portland, OR 97232	503-449-9808
Rules Coordinator	Address	Telephone

RULE CAPTION

Miscellaneous corrections, NRC miscellaneous corrections, individual monitoring devices, and Social Security Number fraud prevention.

RULEMAKING ACTION

ADOPT: N/A

AMEND: 333-105-0560, 333-105-0700, 333-105-0740, 333-113-0210, 333-116-0680, 333-116-0690, 333-116-0720, 333-116-01000, 333-116-1015, 333-118-0070, 333-120-0450, 333-120-0700, 333-120-0710, 333-121-0320, 333-125-0025, 333-125-0080, 333-125-0125, and 333-125-0180.

REPEAL: N/A

Stat. Auth.:
ORS 453.605 – 453.807

Other Authority:

Stats. Implemented:
ORS 453.605 – 453.807

RULE SUMMARY

List each rule number that you are adopting, amending, or repealing and provide a summary of the changes made to each rule.

Amended

OAR 333-105-0560 is amended to be compatible with 10 CFR Parts 47 and 34.83 by removing the requirement that a personnel dosimeter must be processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. The rule amendment also requires when the dosimeter reads greater than two millisieverts and the possibility of radiation exposure cannot be ruled out as the cause, the individual's dosimeter must be sent for processing within 24 hours. Pocket dosimeters found to be off-scale and personnel dosimeter that do not require processing, evaluation of the dosimeter must be started within 24 hours.

OAR 333-105-0700 is amended by replacing the terms film badge and TLD processor to personnel dosimeter throughout the rule.

OAR 333-105-0740 is amended to be compatible with 10 CFR Part 34.101 by inserting Radiation Protections Service's address to report activities performed that are not listed within the licensee's radioactive material license.

OAR 333-113-0210 is amended to be compatible with 10 CFR Part 39.65 by removing the requirement that a personnel dosimeter must be processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor.

OAR 333-116-0680 is amended to be compatible with 10 CFR Part 35.3910 by changing the title of an eligible training program from the Committee on Post Graduate Training of the American Osteopathic Association to Council on Postdoctoral Training of the American Osteopathic Association.

OAR 333-116-0690 is amended to be compatible with 10 CFR Part 35.490 by changing the title of an eligible training program from the Committee on Post Graduate Training of the American Osteopathic Association to Council on Postdoctoral Training of the American Osteopathic Association.

OAR 333-116-1000 is amended to be compatible with 10 CFR Part 35.3045 by removing the word “and” and inserting “or” at the end of subsection (1)(a)(A). In addition, new rule language will direct the licensee reporting a medical event to identify the individual who was subject with the event, be identified by their social security number or an identification number issued by the licensee.

OAR 333-116-1015 is amended to be compatible with 10 CFR Part 35.3047 by adding new rule language to direct the licensee reporting a medical event to identify the individual who was subject with the event, be identified by their social security number or an identification number issued by the licensee.

OAR 333-118-0070 is amended to be compatible with 10 CFR Part 71.17 by changing the recipient’s name to U.S. Nuclear Regulatory Commission (NRC), Document Control Desk Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards when notifying the NRC when using a transportation package for the first time.

OAR 333-120-0450 is amended to be compatible with 10 CFR Part 20.1906 by adding the Authority’s notification telephone number 1-800-452-0311 when removable radioactive surface contamination exceeds the regulatory limits.

OAR 333-120-0700 is amended to be compatible with 10 CFR Part 20.2201 by adding additional language of licensees having an installed Emergency Notification System to make reports to the NRC Commission Operations Center in accordance with 10 CFR, Part 50.72; and
All other licensees shall make reports by telephone to the Authority at 1-800-452-0311.

OAR 333-120-0710 is amended to be compatible with 10 CFR Part 20.2202 by adding additional language of licensees having an installed Emergency Notification System to make reports required by sections (1) and (2) of this rule to the NRC Operations Center in accordance with 10 CFR 50.72; and Reports made by licensees, or registrants, in response to the requirements of sections (1) and (2) of this rule must be made by telephone to the Authority at 1-800-452-0311

OAR 333-121-0320 is amended to be compatible with 10 CFR Part 36.55 by removing the requirement that a personnel dosimeter must be processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program processor. In addition, within the rule, the licensee will now be required to evaluate personnel dosimeters at least quarterly or promptly after replacement, whichever is more frequent.

OAR 333-125-0025 is amended to be compatible with 10 CFR Part 37.23 by adding the statement “the licensee shall provide the oath or affirmation certifications to the Authority, attention: Radiation Protection Services, 800 NE Oregon Street, Suite 640, Portland, Oregon 97232” within this rule.

OAR 333-125-0080 is amended to be compatible with 10 CFR Part 37.27 by revising the addresses that fingerprint cards must mailed for processing and the email address used to obtain additional fingerprint cards. The address to submit fingerprint cards to is U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, Attn: Criminal History Program/Mail Stop – T-07D04M, Maryland 20852. To request additional fingerprint cards, the email address is MAILSVS.Resource@nrc.gov.

OAR 333-125-0120 is amended to be compatible with 10 CFR Part 37.43 by inserting the statement “implementation procedures, or the list of individuals that have been approved for unescorted access” throughout this rule.

OAR 333-125-0125 is amended to be compatible with 10 CFR Part 37.45 by requiring the licensee to report in writing and submitted to Radiation Protection Services when coordination cannot be obtained with the local law enforcement agency regarding responds to threats at the licensee’s facility.

OAR 333-125-0180 is amended to be compatible with 10 CFR Part 37.77 by requiring the licensee to notify the authority in writing when category one materials are being transported through the state of Oregon.

Last Day for Public Comment: by 5:00PM PDT

Secretary of State
STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Oregon Health Authority, Public Health Division

333

Agency and Division

Administrative Rules Chapter Number

Miscellaneous corrections, individual monitoring devices, and Social Security Number fraud prevention.

In the Matter of: Amending rules in Oregon Administrative Rules (OAR) chapter 333, divisions 105, 113, 116, 118, 120, 121, and 125 pertaining to Radiation Protection Service's (RPS) Radioactive Material program.

Statutory Authority: ORS 453.605 – 453.807

Stats. Implemented: ORS 453.605 – 453.807

Need for the Rule(s):

The Oregon Health Authority, Public Health Division, Center for Health Protection, Radiation Protection Services (RPS), is proposing rulemaking to Oregon Administrative Rules (OAR).

The radioactive materials program is proposing rulemaking amendments that will be compatible with the Nuclear Regulatory Commission's federal regulations 10 CFR Parts 47, 34.83, 34.101, 39.65, 35.3910, 35.490, 35.690, 35.3045, 35.3047, 71.17, 20.1906, 20.2201, 20.2202, 36.55, 37.23, 37.27, 37.43, 37.45, and 37.77.

Proposed rulemaking will no longer require licensees to have a personnel dosimeter processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. In addition, the licensee will be required to process a personnel dosimeter within 24 hours when the dosimeter reads greater than two millisieverts and the possibility of radiation exposure cannot be ruled out as the cause. Pocket dosimeters found to be off-scale and personnel dosimeter that do not require processing, must be evaluated within 24 hours of the discovery.

Amended rules changes the terms from film badge and TLD processor to personnel dosimeter and changes the title of an eligible training program from the Committee on Post Graduate Training of the American Osteopathic Association to Council on Postdoctoral Training of the American Osteopathic Association.

Relating to the use of radionuclides in the healing arts, amended rules will make minor miscellaneous corrections for reporting medical events and direct the licensee reporting a medical event to identify the individual who was subject with the event by their social security number, or an identification number issued from the licensee. Amended rules will also require the licensee to submit an oath or affirmation certification to the Authority of the reviewing official's background investigation.

Amended rules revises the mailing address where fingerprint cards are to be submitted and to request additional cards. Category one and two licensees must notify the Authority if they are unable to coordinate with the local law enforcement agencies relating to responses to threats received at the licensee's facility and requires a licensee to notify the Authority when they are transporting category one materials through the state of Oregon.

Documents Relied Upon, and where they are available:

Oregon Revised Statutes ORS 453.605 – 453.807:

https://www.oregonlegislature.gov/bills_laws/ors/ors453.html

[United States Nuclear Regulatory Commission, Review Summary Sheets for Regulation Amendments \(RATS\)](#)

RATS 2018-3: <https://scp.nrc.gov/regulationtoolbox/2018-3.docx>

RATS 2019-1: <https://scp.nrc.gov/regulationtoolbox/2019-1.docx>

RATS 2019-2: <https://scp.nrc.gov/regulationtoolbox/2019-2.docx>

RATS 2020-1: <https://scp.nrc.gov/regulationtoolbox/2020-1.docx>

RATS 2020-2: <https://scp.nrc.gov/regulationtoolbox/2020-2.docx>

RATS 2020-3: <https://scp.nrc.gov/regulationtoolbox/2015-3.docx>

Statement Identifying How Adoption of Rule(s) Will Affect Racial Equity in This State:

Proposed rulemaking is to ensure that all Oregonians, citizens, and communities are afforded with compatible state and federal laws design to protect all persons from unnecessary radiation exposure.

Fiscal and Economic Impact:

RPS does not anticipate causing any fiscal impacts by amending OARs within divisions 105, 113, 116, 118, 120, 121, and 125.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

There will be no additional cost of compliance to the Center of Health Protection, Radiation Protection Services by amending these rules.

2. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:

RPS does not possess the data to determine how many small businesses providing X-ray and radioactive materials services will be subject to these rules. Small businesses will not be negatively impacted by these proposed amended rules.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

Licensees will not experience increased administrative activities with the proposed rule amendments.

c. Equipment, supplies, labor, and increased administration required for compliance:

No additional supplies, labor or administrative oversight will be required for compliance with these proposed rules.

How were small businesses involved in the development of this rule?

Small businesses were not involved in the development of these rules.

Administrative Rule Advisory Committee consulted?: Yes – The Radiation Advisory Committee served as the rule advisory committee for this rulemaking.

If not, why?:

Signature

Printed name

Date

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310.

PROPOSED OREGON BOARD OF MEDICAL IMAGING (OBMI) RULE FOR EXTREMITY CT

Brent Herring



- OAR 337-010-0011(1)(b)
 - (1)(a) Diagnostic Computed Tomography: A licensee who operates computed tomography (CT) equipment, including cone beam CT for diagnosis, must be credentialed in Computed Tomography (CT) by either the American Registry of Radiologic Technologists or the Nuclear Medicine Technology Certification Board or have an active temporary CT license issued by OBMI.
 - (b) Notwithstanding Paragraph (1), a licensee, with a radiography credential from the American Registry of Radiologic Technologists (ARRT), may operate an Extremity Computed Tomography (ECT) machine without having earned a computed tomography credential.
- Proposed rule change
 - (10) "Extremity Computed Tomography Machine" (ECT) means a machine that is specifically designed, with a maximum setting of ~~120kVp at 60 mAs~~
 - **140 kVp at 200mAs**, to perform computed tomography (CT) exams on extremities only. For the purpose of extremity computed tomography only, "extremity" includes the following body parts:
 - (a) Lower extremities including toe; foot; calcaneus; ankle; tibia; fibula; knee; patella; and **distal** femur.
 - (b) Upper extremities including finger; hand; wrist; forearm; elbow; and distal humerus.



LUNCH



EMERGENCY PREPAREDNESS/RESPONSE

Hillary Haskins



PUGET SOUND NAVAL SHIPYARD – NUCLEAR CORE COMPARTMENT INSPECTION AND TOUR

FEMA – REHEARSAL DRILL



- September 20th
 - Switched to CBRN Responder application with great success
 - “Not only did the OR RERT teams perform ingestion pathway sampling well they would easily be able to perform plume sampling.”
 - Really impressed with dedication, quality, and frequency of training.
 - Impressive level of professionalism with internal and external teams (i.e. CST and ODOE)
- Full drill held in Hermiston Oct 24-25th



RADIATION OPERATIONS SUPPORT SPECIALIST (ROSS)

- Radiation Operations Support Specialist
 - Two certified ROSS on Region X
 - Local class held at Oregon State University or OHA in February 2023
 - RPS RERT
 - ODOE staff
 - 102nd CST





UKRAINE NUCLEAR POWER PLANT MONITORING

David Howe

**NUCLEAR SAFETY, SECURITY
AND SAFEGUARDS IN UKRAINE**

**2nd Summary Report
by the Director General**

28 April – 5 September 2022



FIRST REPORTS OF KNOWN OR SUSPECTED RELEASE

No Unusual Radiation Levels Detected in the US; Monitoring is Ongoing

- EPA is following the situation regarding the impact of military actions on the operation of nuclear power facilities in Ukraine.
- EPA continuously monitors radiation levels in the United States through our nationwide RadNet system, and the system is not detecting any unusual levels of radiation.
- There is currently no threat to public health in the United States or its territories and no need to take any protective actions.
 - Do not take potassium iodide (KI) or give it to others unless you have been specifically advised to do so by the health department, emergency management officials or your doctor. KI is issued only in situations where radioactive iodine has been released into the environment, and it protects only the thyroid gland. It is not an “anti-radiation” drug.

Air monitoring by RadNet at www.epa.gov/radnet

U.S. State Department website: www.state.gov.

- EPA’s RadNet system does not include any international monitoring stations but is capable of detecting radiation from overseas incidents.
 - In 1986, EPA detected radiation from the Chornobyl (Chernobyl) accident. The levels of radioactivity were well below levels that could pose a public health threat or require any action. Similarly, in 2011, EPA’s RadNet system detected radiation from the Fukushima incident at stations in the United States.
 - Radiation, as with other air pollution, will travel through the atmosphere between continents, generally over a period of several days.
 - EPA does not have enough information at this time to estimate whether any radiation released from the XNPP will be large enough to be detected in the US.
 - EPA will continue to publicly report all RadNet data on our website

UKRAINE – NO RADIATION RELEASE

- EPA is following the situation regarding military actions near nuclear power facilities in Ukraine.
- EPA continuously monitors radiation levels in the United States through our nationwide RadNet system, and the system is not detecting any unusual levels of radiation.
 - The RadNet system periodically updates radiation air monitoring levels throughout the day on our website, www.epa.gov/radnet.
- For more information on the situation in Ukraine, please visit the U.S. State Department website at www.state.gov.
- While EPA's RadNet system does not include any international monitoring stations, it is sensitive enough to detect radiation in the United States from overseas incidents.
 - EPA's monitoring system detected radiation from the 1986 Chornobyl (Chernobyl) and the 2011 Fukushima nuclear power plant accidents. The amount of radioactivity in the United States from these events was well below levels that could pose a public health threat or require any protective action.
 - Since Fukushima, EPA has significantly enhanced the number of monitoring stations and their capabilities. RadNet has 140 radiation air monitors in 50 states and runs 24 hours a day, 7 days a week. For more information on RadNet, please visit www.epa.gov/radnet/learn-about-radnet.



NEW BUSINESS



2023 HYBRID RAC MEETINGS

David Howe



PUBLIC COMMENTS



THANK YOU FOR ATTENDING

NEXT MEETING IS FEBRUARY 15, 2023