

Department of Human Services Health Services

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Josephine Piccone, Deputy Director Office of State and Tribal Programs U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Subject: Response to your Letter dated October 16, 2002 (Concerning the Oregon Agreement State Program IMPEP Review Conducted August 26-30, 2002)

Dr. Piccone,

As an Agreement State, the State of Oregon has a responsibility to license and monitor the receipt, use and disposal of radioactive materials to protect the health and welfare of its citizens. To accomplish this task, legislation was passed giving Oregon Health Services statutory authority to develop rules and procedures to license and monitor radioactive materials. Radiation Protection Services is the Section charged with implementing the radioactive materials program. We look forward to, and appreciate, reviews of the licensing and inspection program.

As detailed in your report, the Integrated Materials Performance Evaluation Program (IMPEP) team provided a through examination of our program for the period of August, 1998 through August, 2002.

While the report reflects the current status of the program, it does not address the opportunity to exchange ideas on how to fine tune various aspects of the program. Oregon is grateful for the professional approach the team took in providing these insights. In the report there were two issues we would like to address. The team expressed a concern about Advanced Authorizations (also called Verbal Authorizations) and incident reporting.

For the first issue, Advanced Authorizations are typically used to allow licensees to order and receive radioactive materials prior to a license or license amendment being issued. This is primarily to assist licensees because of the lag time between ordering materials and actual receipt. Other types of Advanced Authorizations include new authorized users and temporary change in storage location. In the past this process has been informal and performed by either the licensing or inspection staff as required.

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Based upon the IMPEP Team's recommendations, a procedure has now been developed to formalize this process and include the types of safety considerations found in our normal licensing process. Key points in the revised process are that Advanced Authorizations will require management review and sign-off, they will expire in 30 days (this will reduce the length of time to issue the license or license amendment) and appropriate health and safety restrictions will be included in the authorization.

The second issue deals with incident reporting. The IMPEP team expressed concern about two incidents that may not have been reported timely nor were they properly categorized. Our review of the incident involving I-125 seeds indicates that it should not have been reported as "lost radioactive material".

One incident involved a prostate cancer patient who had been implanted with approximately 130 seeds. A few weeks later, his bladder was being operated on and the surgeon noticed the prostate was significantly abnormal so he removed the prostate. It was sent to pathology to determine if it was cancerous. The pathologist noticed the I-125 seeds when he tried to cross section the tissue for examination. He removed all the seeds he could find. There were just over 100 seeds. It is not unusual for seeds to be discharged by the patient while urinating. Since this is to be expected, we did not consider them "lost" in the usual sense.

The other incident was evaluated by the IMPEP team to be an AO type incident. Upon review of the criteria, they concluded that it was caused by a procedure failure. This incident involved a radiography crew performing field radiography. When the inspector arrived at the site, the crew did not have a working survey instrument or proper dosimetry and their 2 mr/hr line was only on one side and less than 6 feet away from the valve being radiographed. There were also several other items of non-compliance. At the time of this incident, we did not feel this was a procedure failure, but rather gross negligence on the part of the radiography crew and reported this as an incident rather than a 24 hour notification.

In both cases, we have reviewed the reporting requirements and agree that they should have been reported to the NRC in a more timely manner. We will make every attempt to properly evaluate incidents and report them to the NRC as required in SA-300. During the first quarter of calender year 2003, we will also review all NMED reporting requirements against our current system of data recording and transfer to INEEL and make all necessary changes to provide fully compatible data for national materials event

reporting for the benefit of all concerned.

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We have also enclosed our comments concerning your review of our draft rules. We anticipate having them submitted to the DHS-Health Services Administrator by November 22, 2002 and they should be to the Secretary of State's Office no later than the second week of December.

We appreciate the IMPEP team's thoroughness in conducting this valuable program review. We gained significant insight about our program and have implemented many of their useful suggestions. Should you have any questions concerning this correspondence, please contact Terry Lindsey at 503/731-4014 x660 or Ed Wright at 503/731-4014 x679.

Sincerely,

Grant K. Higginson, M.D.

Acting Administrator

Department of Human Services

Office of Health Services

Enclosure

Copy to: Terry D. Lindsey, RPS Section Manager

NRC Chronology Identification	FR Notice (State Due Date)	RAT S ID	P/F*	NRC Review	Final State Regulation	Comments
Standards for Protection Against Radiation-Part 20	56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94)	1991-3	F	N 11/13/9 7		1995 [333-120]
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991- 1				1995 By reference to 34.20 & 34.21 [333-105-0110(5)]
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991- 4				1995 Part 20 addressed in 333- 120-700, -710 and -720
Quality Management Program and Misadministration s-Part 35	56 FR 34104; (1/27/95)	1992- 1				1995 [333-116-0125]
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992- 2			Not required 3	N/A
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993- 2			Not applicable SECY-95- 112 4	New 2002 [333-121]
Definition of Land Disposal and Waste Site QA Program- Part 61	58 FR 33886; (7/22/96)	1993- 3			Not applicable SECY-95- 112 4	N/A
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993- 3			Not applicable SECY-95- 112 4	N/A

NRC Chronology Identification	FR Notice (State Due Date)	RAT S ID	P/F*	NRC Review	Final State Regulation	Comments
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994- 1			Not required 3	N/A
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards- Part 40	59 FR 28220; (7/1/97)	1994- 2				Office of Energy [OAR 345-92 and OAR 345-95]
Timeliness in Decommissioning Material Facilities- Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994- 3				1995 10 CFR 30.35 and 30.36 referenced in 333-102-200(6)
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767; 59 FR 65243 60 FR 322; (1/1/98)	1995-1				1. Human research - Broad Scope A - RSC follows approved procedure and requires a Human Research Committee. Other licensees done by license condition and also requires a Human Research Committee. 2. License required - in rule. Additional comments at end of this enclosure note (1).
	L		l	<u> </u>	<u> </u>	
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995- 2				No licensee in Oregon requires respiratory protection for licensed activities. 333-120-0320 requires Agency notification 30 days before use of respiratory protection. RPS will require licensee to follow current NRC regulations.
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995- 3				1995 120-0550 references LLW manifest requirements in 10 CFR 20. Needs to have Appendix F changed to Appendix G.

NRC Chronology Identification	FR Notice (State Due Date)	RAT S ID	P/F*	NRC Review	Final State Regulation	Comments
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995- 4				Implemented in licensing. All radiography cameras used in state were reviewed. Those not meeting standards were either disposed or placed in storage.
Radiation Protection Requirements: Amended Definitions and Criteria- Parts 19,	60 FR 36038; (8/14/98)	1995- 5				Part 19 requirements already in place 1995. Also more restrictive as to who is required to receive training. Division 120 wording is similar to Part 20, intent is identical.
Clarification of Decommissioning Funding Requirements- Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995- 6				1995 10 CFR 30.35 and 30.36 referenced in 333-102-200(6)
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995- 7				Part 20 changes 1995 in 333-120-0010 and 333-100- 0005(86) & (95) Part 35 changes 1995 in 333- 116-0130 Note: "patient" retained
10 CFR Part 71: Compatibility with the International Atomic Energy Agency- Part 71	60 FR 50248; 61 FR 28723 (4/1/99)	1996- 1				OAR 333-118 references 49 CFR. Oregon implements 49 CFR regulations by license condition
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996- 2			Not required 3	N/A
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997- 1				1995 333-120-0560 Compliance with Environmental and Health Protection Regulations. Oregon uses this rule to implement EPA standards (as well as others). Public exposures from operations must be <10 mr per year

NRC Chronology Identification	FR Notice (State Due Date)	RAT S ID	P/F*	NRC Review	Final State Regulation	Comments
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997- 4			Not required 3	N/A
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2				1995 333-102-0340 and by license condition.
Criteria for the Release of Individuals Administered Radioactive Material- Parts 20, 35 62 FR 4120; (5/29/00) 1997-3						New 2002. Currently implemented by variance request.
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations- Parts 30, 34, 71, 150	62 FR 28948; (6/27/00)	1997-5				2002 fully implemented. Currently accomplished by license conditions.
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39058; (8/20/00)	1997- 6				Criteria implemented by license condition. Limits are considered maximums and licensees are required to meet ALARA.

NRC Chronology Identification	FR Notice (State Due Date)	RAT S ID	P/F*	NRC Review	Final State Regulation	Comments
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea- Part 30	62 FR 63634; (1/02/01)	1997- 7				Exempt distribution addressed in 333-102-0035
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998- 1				2002 fully implemented 333- 100-0080
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998- 2			Not required 3	N/A
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998- 3			Not required 3	N/A
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998- 4				2002 fully implemented
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998- 5				2002 fully implemented
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-				333-120-0550 references 10 CFR 20 requirements. Needs Appendix F corrected to Appendix G.

NRC Chronology Identification	FR Notice (State Due Date)	RAT S ID	P/F*	NRC Review	Final State Regulation	Comments
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999- 1				None in Oregon
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)			1999-2	Not required 3	N/A
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55525 (2/2/03)	1999- 3				Will be addressed 2003
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1				Will be addressed 2003
New Dosimetry Technology Parts 34, 36, 39	65 FR 63749; (1/8/04)	2000-				Will be addressed 2003

Note (1)

36.610 In rule 1995 333-116-510

36.615 (d) & (e) In rule 1995

333-116-540 (4) & (5)

35.900 116-640 Not specifically in rule however, have not denied any appropriate board certified physician or medical physicist.

35.910

116-660 Not specifically in rule. However, have not had any physicians from the newly listed boards apply for privileges.

35.920 116-670 One board not included

35.920 (8)(2)(iii) in rule 1995 333-116-680

35.930 116-680 Boards listed in (3) & (4) not in rule. However, we have not had any physicians from either board apply for privileges.

35.950 116-710 board listed in (4) not in rule. See 35.930

35.960 In rule 1995 333-116-720

35.961 In rule 1995 333-116-730

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35.972 In rule 1995 333-116-760
             Note: OR requires <5 years for recentness of training. NRC requires <7.
35.980 Not in rule. Only board certified nuclear pharmacists authorized in licensing.
35.981 Not in rule
                    Only board certified nuclear pharmacists authorized in licensing.
35.991 Not required.
32.72 333-102-285 Similar, however, needs editing to be same.
(1) (c)
             Supervision - 333-116-100
             Exemptions - Type A in 333-102-900(2)
             QMP -In rule 1995 333-116-125(1)(6)
             For human research & patient we look at all administrations.
35.33 In Rule 1995 333-116-130
35.49 In rule 1995
                     333-116-140 General statement referring to sealed and unsealed sources.
35.50
             In rule 1995 33-116-160
35.52 Dose calibrators for a & b – emitting radionuclides by license amendment.
35.53 In rule 1995 333-116-180
35.60 In rule 1995 333-116-210 & 220
35.75 In rule 1995 333-116-260
35.100 Oregon rule more is more restrictive in that it must be a FDA approved drug. Oregon rule
      does not address manufacturing or pharmacy, neither does the license. However, it is
      reviewed during the inspection. No license has received or used materials contrary to
      35.100
35,200 see 35,100
35.300 see 35.100
35.310 In rule 1995 333-116-370
35.315 In rule 1995 333-116-380
35.404 In rule 1995 333-116-460
35.406 In rule 1995 333-116-450
35.410 In rule 1995 333-116-430
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35.415 In rule 1995 333-116-440

COMMENTS ON PROPOSED OREGON REGULATIONS AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
105- 0005(49)	34.3	None	В	Definitions: Storage container The state changed 'secured and stored' to 'transported or stored.' This alteration changes the meaning of the definition by substituting the word 'secured' with 'transported.' <u>'Transported' will be changed to 'stored'.</u>
100-0005	71.4	None	В ′	Definitions: A1 The State omitted this definition. Found at 333-118-0020(17)
100-0005	71.4	None	В	Definitions: Package The State omitted this definition Found at 333-100-0005(91)
100-0005	30.4	None	A	Definitions: Alert The State omitted this definition. Not in SSR's. Oregon does not have any licensees to which this definition would apply.

102- 0203(70)	30.4	None	A	Definitions: Special nuclear material The State's definition is incomplete. 10 CFR 30.4 'Special Nuclear Material' means special nuclear material as defined in Part 70. 100-0005(133) identical to Part 70 Definition. 102-0203(70) and (71) will be edited to reflect the intent of Division 102 (Licensing)
102-0010	30.14	None	В	Exempt concentrations The State has omitted the manufacturing exemption found in 30.14 (c) and (d). Because of the implications of 30.14(c), we will add in 2003 to allow public comment. 30.14(d) can be found at 102-0010(2)
102-0030	30.19	None	В	Self-luminous products containing tritium, krypton-85, or promethium-147 The State omitted "persons who initially transfer for sale or distribution" when listing the exceptions to the exemptions listed in this section as stated in 30.19(a) 'persons who initially transfer for sale or distribution' will be added to 102-0030

102-0025	30.20	None	В	Gas and aerosol detectors containing byproduct material The State omitted "persons who initially transfer for sale or distribution" when listing the exceptions to the exemptions listed in this section as stated in 30.20(a) 'persons who initially transfer for sale or distribution' will be added to 102-0025
102-0075	30.31	None	С	Types of licenses The State has omitted the reference to "specific" licences. 102-0075(2) Stricken text will be undeleted
33-100-0005	20.1003	1998-5	A	Definitions: Declared pregnant woman The State omitted the last part of the definition for declared pregnant woman that reads "The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant' will be added. Note: This statement is in our "Instruction Concerning Prenatal Exposure" guide.
33-120-0100	20.1201	1998-5	A	Occupational dose limits for adults The State did not change the phrase "eye dose" to "lens dose" in 0100 (b) (A) "Eye dose" will be changed to "lens dose"

33-120-0100	20.1208	1998-5	Α	Dose to an embryo/fetus
				The State does not include the word "equivalent" the section as required by 20.1208
				'Equivalent' will be added where necessary.
33-120-0600	20.2101	1998-5	С	General provisions
				The State did not change "eye dose" to "lens dose" through out the entire section 33-120.
				"Eye dose" will be changed to "lens dose" where necessary
33-120-0020	20.1101	1998-5	D H/S	Radiation protection programs
				The State did not change the word "Practicable" to "Practical"
				'Practicable' is the grammatically correct word to use in this situation. Note this is a "D" and is not required for compatibility.
33-120-0210 (1)(b) and (2) (b)	20.1502	None	D H/S	Conditions requiring individual monitoring of external and internal occupations dose
				The time period for the declared pregnant women exposure limit is stated as one year. The correct time period is "for the length of the pregnancy"
				This will be corrected by following 20.1502 format and separate minors from declared pregnant women.

333- 113-0115	39.33	None	С	Radiation detection instruments The State did not change the milliroentgens to millirem Division 113 was not amended during this revision and was inadvertently submitted for review. This will be addressed in 2003.
333-120- 0180	20.1301 (a) (1)	None	A	Dose limits for individual members of the public The State did not include the following in the paragraph "exclusive of the dose to individual members of the public from background radiation, from any medical administered radioactive material and released in accordance with 10 CFR 35.75, from voluntary participation in medical research programs and" This statement will be added.
333-116- 0030	35.11	1995-1	С	License Required The State omitted the licensing requirements as stated in 35.11 (c). Although not included as a definition it does appear in 116-0300(1)(b), 116-0320(1)(b) and 116-0360(1)(b). It is also included in each medical license as a standard license condition.
333-120- 0005	20.1003	1997-1	С	Definitions: Constraint (Dose Constraint) The State has omitted this definition Not considered necessary. This issue is addressed during licensing in ALARA programs. If necessary, this can be addressed in 2003.

333-120- 0020	20.1101	1997-1	С	Radiation Protection Programs
0020				The State omitted the requirements of paragraph 20.1101(d) including the Radon-222 exclusion.
			·	This will be addressed in 2003. Note that we utilize EPA release requirements for licensees that may exceed release limits. Licensees are required to demonstrate annual releases will not result in off-site exposures greater than 10 mrem/year.
333-120- 0550	20.2006	1995-3	В	Transfer for Disposal Manifests
				The State references Part 20 Appendix "F" in this section. Appendix "F" has been deleted from Part 20. The correct reference is Part 20 Appendix "G"
				Appendix "F" will be changed to Appendix "G".
333-120- 0550	20.2006	1995-3	В	Transfer for Disposal Manifests
				The State has omitted the requirements of 20.2006 (b)
				Appendix "F" will be changed to Appendix "G". Note: Although the wording is not identical it says the same thing as 20.2006(b).
333-102-306	40.36	1995-6	H&S	Financial assurance and recordkeeping for decommissioning
			·	The State does not include the requirements for Financial assurance and recordkeeping for decommissioning for source material.
				333-102-0306 has been deleted and all references to 10 CFR requirements retained.

333-102-306	40.42	1995-6	H&S	Expiration and termination of licenses and de-commissioning of sites and separate or outdoor areas The State does not include the requirements for expiration and termination of licenses and decommissioning of sites and separate or outdoor areas for source material. 333-102-0306 has been deleted and all references to 10 CFR requirements retained.
333-102-306	70.25	1995-6	H&S	Financial assurance and recordkeeping for decommissioning The State does not include the requirements for Financial assurance and recordkeeping for decommissioning for special nuclear material. 333-102-0306 has been deleted and all references to 10 CFR requirements retained.
333-102-306	70.38	1995-6	H&S	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas The State does not include the requirements for expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas for special nuclear material. 333-102-0306 has been deleted and all references to 10 CFR requirements retained.

333-120- 0550	20.2006 and Part 20 Appendix G	1998-6	В	Requirements for Low-level radioactive waste intended for disposal at land disposal facilities and manifests The State did not incorporate the change as required by this amendment, RATS ID 1996-6. The State references the old appendix "F" as the guide for this section. Appendix "F" was removed as an option for manifest requirements. Appendix "G" is the correct appendix to reference for this section. Appendix "F" will be changed to Appendix "G".
333-120-015 and/or 333-100-005	20.1003	1997-7	_	Definitions
			A	The State did not revise the definition of background radiation as per 20.1003.
				<u>This is word-for-word in 120-0015(7).</u> <u>Will correct 100-0005(15).</u>
			В	The State has omitted the definition of Critical Group.
				Will include.
			С	The State has omitted part of this definition of Decommission.
				This is word-for-word in 120-0015(14). Will correct 100-0005(32).
333-016- 0010	35.2	1995-7	С	Definitions
0010				In amendment, RATS ID # 1995-7, the definition for misadministration was amended by removing the term ``patient or human research subject" and inserting the word ``individual." The State did not make this change. Will correct.

Editorials suggestions

- 1. In 333-100-0005, in the definition of ALARA, "As Los As.." should be "As Low As"
- 2. In 333-100-0005, in the definition of Becquerel, the abbreviation should read "Bq" rather than "Gq"
- 3. In 333-100-0005, in the definition of Gray, the definition should read "an absorbed dose," rather than "and absorbed dose"
- 4. In 116-0020(25), "teletherapy" is misspelled.
- 5. In 333-121-0190(1): The activity is given as 2 x 1017 rather then the scientific notation of 2 x 10^{17} .

All editorial suggestions have been implemented. Thank you.