

June 18, 2010

Terry Lindsey, Program Director
Radiation Protection Services
Oregon Health Services
Department of Human Services
800 NE Oregon Street, Suite 640
Portland, OR 97232-2162

Dear Mr. Lindsey:

We have reviewed the proposed changes to the Oregon regulations, Requirements for Expanded Definition of Byproduct Material, received by our office on April 21, 2010. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, 150, and the requirements of the one amendment identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Todd Carpenter on June 15, 2010.

As a result of our review, we have five comments that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that the Oregon regulations meet the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final Oregon regulations. However, we have determined that if your proposed regulations were adopted, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure [SA-200](#).

We request that, when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in FSME Procedure [SA-201](#), "Review of State Regulatory Requirements," please highlight the final changes, and provide a copy to Division of Materials Safety and State Agreements, FSME.

The SRS Data Sheet summarizes our knowledge of the status of other Oregon regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the FSME website: <http://nrc-stp.ornl.gov/rulemaking.html>.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact Kathleen Schneider, State Regulation Review Coordinator, at (301) 415-2320 (Kathleen.Schneider@nrc.gov) or Maria Arribas-Colon at (301) 415-6026 (Maria.Arribas-Colon@nrc.gov).

Sincerely,

/RA A. Dias for/

Terrence Reis, Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures:
As stated

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DOCUMENT NAME: G:\DMSSA\SAISB\REGULATION TOOLBOX\States\Oregon\10-22

Incoming Document: ML101110618

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COMPATIBILITY COMMENTS ON OREGON PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	333-120-0550 (5)	§20.2006 (e)	2007-3	B	<p>Transfer for disposal and manifests</p> <p>Oregon needs to insert the phrase “in accordance with 10 CFR Part 20 Appendix G” after “...to the intended consignee.”</p> <p>Oregon needs to make the above change to 333-120-0550 in order to meet the Compatibility Category B designation assigned to Section 10 CFR 20.2006 (e).</p>
2	333-102-0190(8)	§30.32(g)	2007-3	C	<p>Application for specific licenses</p> <p>Oregon omits “;or” in 333-102-0190 (8)(b) which is the equivalent regulation to 30.32(g)(2).</p> <p>Oregon omits the phrase “the device; and” in 333-102-0190 (8)(c)(A) which is the equivalent regulation to 30.32 (g)(3)(i).</p> <p>Oregon needs to make the above change to 333-120-0190 in order to meet the Compatibility Category C designation assigned to Section 10 CFR 30.32(g).</p>
3	333-102-0305 (29)	§30.34(j)	2007-3	B	<p>Terms and conditions of licenses</p> <p>Oregon references to their regulation 333-116-0220 (Labeling of Vials and Syringes) in 333-102-0305(29)(2)(a) is not equivalent to 10 CFR 32.72(a)(4).</p> <p>Oregon references to their regulation 333-116-0165 (Possession, Use, Calibration, and Check of Instruments to Measure Dosages of Alpha- or Beta-emitting Radionuclides) in 333-</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>102-0305(29)(2)(b) is not equivalent to 10 CFR 32.72(c).</p> <p>Oregon needs to correct the above references in order to meet the Compatibility Category B designation assigned to Section 10 CFR 30.34(j).</p>
4	333-102-0285 (1)(b) & (2)	§32.72 (a)(2)(i), (iii), (iv), (v), & (b)	2007-3	B	<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs, containing byproduct material for certain in vitro clinical or laboratory testing under general license</p> <p>Oregon omits the word “owner” and the phrase “preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a)” in 333-102-0285 (1)(b) equivalent to 10 CFR 32.72 (a)(2)(i).</p> <p>Oregon omits 10 CFR 32.72(a)(2)(v) (A Positron Emission Tomography (PET) drug production facility registered with a State agency).</p> <p>Oregon needs to make the above changes in order to meet the Compatibility Category B designation assigned to Section 10 CFR 32.72 (a)(2)(i), and (v).</p>
5	333-116-0330	§35.204 (a)	2007-3	H&S	<p>Permissible molybdenum-99 concentrations</p> <p>Oregon did not revise 333-116-0330 to include the equivalent requirements for strontium-82 found in 10 CFR 35.204 (a)(2).</p> <p>Oregon needs to revise 333-116-0330 to meet the Category H&S designation assigned to Section 10 CFR 35.204(a).</p>

STATE REGULATION STATUS

State: Oregon

Tracking Ticket Number: 10-22

[1 amendment(s) reviewed is identified by a ★
at the beginning of the equivalent NRC requirement.]

Date: June 18, 2010

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (Superceded by 1997-5)	01/10/1994	Final ML023450397	No Comments 01/23/2003 ML030240463	Oregon has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 (Superceded by 1997-5)	none	Not Required	Not Required	Oregon has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-3	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;	01/01/1994	Final	No Comments 11/13/1997	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final ML023450397	No Comments 01/23/03 ML030240463	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995	Final ML023450397	No Comments 01/23/2003 ML030240463	Oregon has adopted Final Regulations equivalent to RATS ID: 2002-2.
1992-2	Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions Parts 30, 35 57 FR 45566	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30, 40 58 FR 39628	10/25/1996	Final ML023450397	No Comments 01/23/2003 ML030240463	

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Final ML023450397	No Comments 01/23/2003 ML030240463	
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Final ML100600750	No Comments 04/15/2010 ML100850065	
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1994-2	Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220	07/01/1997	Not Applicable	Not Applicable	Oregon does not have authority to regulate this material under its Agreement.
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026	08/15/1997	Final ML023450397	No Comments 01/23/2003 ML030240463	
1995-1	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	01/01/1998	Final ML023450397	No Comments 01/23/2003 ML030240463	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment	03/13/1998	Not Applicable ¹	Not Applicable	Oregon does not have any licensees subject to these regulations. (See SECY-95-112)
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final ML023450397	No Comments 01/23/2003 ML030240463	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superceded by 1997-5)	06/30/1998	Final ML023450397	No Comments 01/23/2003 ML030240463	Oregon has adopted Final Regulations equivalent to RATS ID: 1997-5.

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final ML071870477	No Comments 09/04/2007 ML072470108	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final ML063110122	No Comments 12/21/2006 ML070030381	
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 (Superceded by 2002-2 and 2005-2)	10/20/1998	Final ML063110122	No Comments 12/21/2006 ML070030381	Oregon has adopted Final Regulations equivalent to RATS IDs: 2002-2 and 2005-2.
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 (Superceded by 2004-1)	04/01/1999	Final ML071870477	No Comments 09/04/2007 ML072470108	Oregon has not yet adopted Final Regulations equivalent to RATS ID: 2004-1.
1996-2	One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses Parts 30, 40, 70 61 FR 1109	02/15/1999	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1996-3	Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61, 70 61 FR 24669	06/17/1999	Final ML023450397	No Comments 01/23/2003 ML030240463	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final ML071870477	No Comments 09/04/2007 ML072470108	
1997-2	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State Part 150 62 FR 1662	02/27/2000	Final ML023450397	No Comments 01/23/2003 ML030240463	

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1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final ML023450397	No Comments 01/23/2003 ML030240463	
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superseded by 2004-1)	02/10/2000	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-97-078)
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71, 150 62 FR 28947	06/27/2000	Final ML073390164	No Comments 12/20/2007 ML073540058	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final ML023450397	No Comments 01/23/2003 ML030240463	
1997-7	Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634	01/02/2001	Final ML063110122	No Comments 12/21/2006 ML070030381	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71,	02/12/2001	Final ML023450397	No Comments 01/23/2003 ML030240463	
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535	07/01/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1998-3		07/10/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074) Oregon has adopted Final Regulations equivalent to RATS ID: 2002-2.
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final ML023450397	No Comments 01/23/2003 ML030240463	

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 35, 36 63 FR 39477; 63 FR 45393	10/26/2001	Final ML073390164	No Comments 12/20/2007 ML073540058	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML063110122	No Comments 12/21/2006 ML070030381	
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	Oregon does not have authority to regulate this material under its Agreement.
1999-2	Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information Part 31 64 FR 42269	10/04/2002	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	Final ML091750761	Comments 07/14/2009 ML091820663	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML071870477	No Comments 09/04/2007 ML072470108	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML063110122	No Comments 12/21/2006 ML070030381	
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct	02/16/2004	Final ML071870477	Comments 09/04/2007 ML072470108	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML063110122	No Comments 12/21/2006 ML070030381	

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Final ML063110122	No Comments 12/21/2006 ML070030381	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Final ML063110122	No Comments 12/21/2006 ML070030381	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Proposed ML091940024	Comments 08/11/2009 ML092100397	
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Final ML063110122	No Comments 12/21/2006 ML070030381	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35	04/29/2008	Final ML063110122	No Comments 12/21/2006 ML070030381	
2005-3	Increased Controls for Risk-Significant Radioactive Sources	12/01/2005	License Condition ML052870028	No Comments 10/18/2005 ML052930002	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70	03/27/2009	Final ML100600750	No Comments 04/15/2010 ML100850065	
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	R ² ML083570002	No Comments 01/13/2009 ML083570028	
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	R ² ML083570002 License Condition ML083660132	No Comments 01/13/2009 ML083570028 No Comments 01/22/2009 ML090120206	
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010			

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, 150 72 FR 58473	12/17/2010	Final ML100600750	No Comments 04/15/2010 ML100850065	
*2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010	Proposed ML101110618	Comments 06/18/2010 ML101390012	
2007-4	Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305 72 FR 70901	06/05/2008	License Condition ML080790556	No Comments 03/27/2008 ML080870332	
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011			
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012			