

March 2, 2011

Roland G. Fletcher, Manager IV
Radiological Health Program
Air and Radiation Management Administration
1800 Washington Boulevard
Baltimore, MD 21230

Dear Mr. Fletcher:

We have reviewed the proposed changes to the Maryland regulations COMAR 26.12.01.01, received by our office on December 21, 2010. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 19, 20, 30, 31, 32, 33, 35, 61 and 150 and the requirements of the two amendments and changes not associated with specific NRC amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Ray Manley on March 1, 2011.

As a result of our review, we have nine 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 Maryland 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 Maryland 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 Maryland 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/

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

Enclosures:
As stated

[Concurrence Page]

Enclosures: As stated

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Incoming Document: ML103550248

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COMPATIBILITY COMMENTS ON MARYLAND PROPOSED REGULATIONS

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	Section C.4(c)(3)(i)	§30.20(a)	2007-3	<p>B</p> <p>Gas and aerosol detectors containing byproduct material</p> <p>It appears that Maryland never authorized the Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors comparable to the provisions found in the Suggested State regulations in C.28(c). Since this area is reserved to NRC, Maryland needs to revise C.4(c)(3)(i) language as follows, including the information in the footnote:</p> <p>“Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in Parts A, C through E, G, J, W, and X to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing byproduct material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC²/ pursuant to 10 CFR 32.26; or an Agreement State pursuant to C.28c., which authorizes the initial transfer of the detectors to persons who are exempt from regulatory requirements. This exemption also covers gas and aerosol detectors</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>manufactured or distributed before November 30, 2007 in accordance with a specific license issued by an Agreement State under comparable provisions to 10CFR 32.26. authorizing distribution to persons exempt from regulatory requirements.”</p> <p>Footnote 21 <i>Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555</i></p> <p>Maryland needs to incorporate the above change to Section C.4(c)(3)(i) in order to meet the Compatibility Category B designation assigned to 10 CFR 30.20(a).</p>
2	Section C.26(g)	§30.32(j)	2007-3	B	<p>Application for specific licenses</p> <p>Maryland regulation Section C.26(g) and C.26(g)(1) references “Section C” instead of “Part C.” Maryland needs to replace “Section” with “Part” when referencing to the entire Part.</p> <p>Maryland needs to make incorporate the above changes to Section C.29(g) in order to meet the Compatibility Category B designation assigned to 10 CFR 30.32(j).</p>
3	Section C.22(l)	§31.12	2007-3	C	<p>General license for certain items and self-luminous products containing radium-226</p> <p>Maryland needs to revise the references to be consistent with Maryland’s codification scheme.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>In C.22(l)(2), Maryland should replace “Section D and J” with “Part D and J.” “Section C” should be revised to “Part C.”</p> <p>In C.22(l)(3)(iv), Maryland needs to change reference “Section C” to “Part C.”</p> <p>In C.22(l)(4), Maryland needs to change the reference from “Section C.22” to “Section C.22(l)(1).”</p> <p>Maryland needs to make the above changes to Section C.22(l) in order to meet the Compatibility Category C designation assigned to 10 CFR 31.12.</p>
4	Section C.28(o)	§32.59	2007-3	B	<p>Same: Leak testing of each source</p> <p>Maryland regulation Section C.28(o) references C.22(d) as equivalent to 10 CFR 31.8. In existing Maryland regulation, C.22(g) is equivalent to 10 CFR 31.8. In C.28(o), Maryland needs to change the reference from “Section C.22(d)” to “Section C.22(g).”</p> <p>Maryland needs to make the above changes in Section C.28(o) in order to meet the Compatibility Category B designation assigned to 10 CFR 32.59.</p>
5	Section C.28 (j)(1)(ii) (a), (c), (d), (e) and (j)(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>In C.28(j)(1)(ii)(a), Maryland omits: “... as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);...” after “Registered or</p>

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					<p>licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;...”</p> <p>Maryland needs to incorporate the above to Section C.28(j)(1)(ii)(a) in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72(a)(2)(i).</p>
6	Section D.301 (d)	§20.1301 (a) and (c)	Not Applicable	A	<p>Dose limits for individual members of the public</p> <p>Maryland on Section D.301(d) states: “Notwithstanding paragraph (a)(1) of this section, ...” The correct reference in this Section per Maryland codification scheme is (a)(i). Maryland needs to list the correct reference to this section.</p> <p>Maryland needs to make the above change to Section D.301(d) in order to meet the Compatibility Category A designation assigned to 10 CFR 20.1301(c).</p>
7	Section C.28(j) (2)(i) & (2)(ii)(b)	§32.72 (b)(1)& (b)(2)(ii)	Not Applicable	B	<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35</p> <p>Maryland regulations on Section C.28(j)(2)(i) states that: “May prepare radioactive drugs for medical use, as defined in Sec. G.2, provided...” instead of “Sec A.2.” The definition of authorized nuclear pharmacist in Maryland regulations is located in Section A.2, not Section G.2. Maryland needs to list the correct reference in this section.</p> <p>Maryland needs to make the above change to Section C.28(j)(2)(i) in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72(b)(1).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
8	Section G.80	§35.80	Not Applicable	H&S	<p>Provision of mobile medical service</p> <p>Maryland proposed regulation would delete language similar to 10 CFR 35.80(a)(3) which addresses the need to check survey instruments for proper operations with a dedicated check source before use at each client's address.</p> <p>Maryland needs to retain the requirements in the existing G.80(a)(3) in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.80.</p>
9	Section D.1208	§35.3045	Not Applicable	C	<p>Report and notification of a medical event</p> <p>Maryland omits equivalent language to 35.3045(b). Maryland needs to add equivalent language into their regulations.</p> <p>Maryland needs to incorporate the above in order to meet the Compatibility Category C designation assigned to 10 CFR 35.3045.</p>

STATE REGULATION STATUS

State: Maryland

Tracking Ticket Number: 10-56

[2 amendment(s) and changes not associated with RATS ID reviewed are identified by a ★ at the beginning of the equivalent NRC requirement.]

Date: March 2, 2011

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (Superceded by 1997-5)	01/10/1994	Final	No Comments 09/09/1995	Maryland 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	Final	No Comments 09/09/1995	Maryland 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 02/28/1997	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final	No Comments 04/15/1998	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995	Final	No Comments 09/09/1995	Maryland has not yet 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	No Comments 10/19/1995	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Final	No Comments 03/20/1997	
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable ¹	Not Applicable	Maryland does not have any licensees subject to these regulations. (See SECY-95-112)
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	Maryland 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	No Comments 08/08/2000	
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	No Comments 08/08/2000	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Final	No Comments 11/03/1997	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final	No Comments 12/28/1997	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superceded by 1997-5)	06/30/1998	Final	No Comments 08/08/2000	Maryland has adopted Final Regulations equivalent to RATS ID: 1997-5.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final	No Comments 08/08/2000	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final	No Comments 08/08/2000	
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 (Superseded by 2002-2 and 2005-2)	10/20/1998	Final	No Comments 08/08/2000	Maryland has not yet 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 (Superseded by 2004-1)	04/01/1999	Final	No Comments 08/08/2000	Maryland 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	No Comments 08/08/2000	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final ML051380408	No Comments 06/27/2005 ML051800055	
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 ML051380408	No Comments 06/27/2005 ML051800055	

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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 ML021120426	No Comments 05/10/2002 ML021340513	
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 ML021120426	No Comments 05/10/2002 ML021340513	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final ML021120426	No Comments 05/10/2002 ML021340513	
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 ML051380408	No Comments 06/27/2005 ML051800055	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150 63 FR 1890; 63 FR 13773	02/12/2001	Final ML051380408	No Comments 06/27/2005 ML051800055	
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	License Term for Medical Use Licenses Part 35 63 FR 31604 (Superseded by 2002-2)	07/10/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074)

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final ML051100241	No Comments 05/13/2005 ML051360003	
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 ML051100241	No Comments 05/13/2005 ML051360003	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML051100241	No Comments 05/13/2005 ML051360003	
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not applicable	Maryland 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 ML051100241	No Comments 05/13/2005 ML051360003	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML051100241	No Comments 05/13/2005 ML051360003	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML071710580	No Comments 09/04/2007 ML072470495	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31, 32 65 FR 79162	02/16/2004	Final ML071980288	No Comments 08/03/2007 ML072210120	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML071710580	No Comments 09/04/2007 ML072470495	
2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Final ML083290007	No Comments 12/23/2008 ML083460488	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Final ML071710580	No Comments 09/04/2007 ML072470495	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML093500525	No Comments 01/27/2010 ML100140061	
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Final ML083290007	No Comments 12/23/2008 ML083460488	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926	04/29/2008	Final ML083290007	No Comments 12/23/2008 ML083460488	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML053040172	No Comments 11/01/2005 ML053050373	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Final ML093500525	No Comments 01/27/2010 ML100140061	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Final ML093500525	No Comments 01/27/2010 ML100140061	
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	Proposed ML082108398 License Condition ML083390004	No Comment 09/03/2008 ML082310168 No Comment 12/11/2008 ML083390024	
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Final ML093500525	No Comments 01/27/2010 ML100140061	
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	Proposed ML101690102	No Comments 07/29/2010 ML101800106	
*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 ML103550248	Comments 03/02/2011 ML110240010	
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 ML081160371	No Comments 05/02/2008 ML081230186	
*2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011	Proposed ML103550248	No Comments 03/02/2011 ML110240010	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012			
N/A	10 CFR 20.1301, 32.72, 35.80 and 35.3045	N/A	Proposed ML103550248	Comments 03/02/2011 ML110240010	

¹ IMPEP Team: verify that Maryland does not have any licensees subject to these regulations during each review.