

June 25, 2008

John Parker, Chief
Radiation Control Bureau
Field Operations Division
Environment Department
Harold S. Runnels Building
1190 St. Francis Drive, Room S2100
P.O. Box 26110
Santa Fe, NM 87502-0110

Dear Mr. Parker:

We have reviewed the proposed changes to the New Mexico regulations, Radiation Protection Rules 20.3 NMAC, received by our office on May 2, 2008. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 31, 32, 35, 40, 61, 70, 71, 150 and the requirements of the 11 amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Daniela Bowman on June 25, 2008.

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 New Mexico 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 New Mexico 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 New Mexico 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 (email: kathleen.schneider@nrc.gov) or Monica Orendi at (301) 415-3938 (email: monica.orendi@nrc.gov).

Sincerely,

/ RA /

James G. Luehman, 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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Sincerely,

/ RA /

James G. Luehman, 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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COMPATIBILITY COMMENTS ON *NEW MEXICO* PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	20.3.7.704	35.100	2002-2 2005-2 2006-1	H&S	<p>Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required</p> <p>New Mexico lists the wrong references in 20.3.7.704.B(2). The cross references should be “in either subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 35.290, or Subsection H of 20.3.7.714 NMAC, incorporating 10 CFR 35.390, and Subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 290(c)(1)(ii)(G); ...”.</p> <p>New Mexico needs to make the above change in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.100.</p>
2	20.3.7.705	35.200	2002-2 2005-2 2006-1	H&S	<p>Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required</p> <p>New Mexico lists the wrong references in 20.3.7.705.B(2). The cross references should be “in either subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 35.290, or Subsection H of 20.3.7.714 NMAC, incorporating 10 CFR 35.390, and Subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 290(c)(1)(ii)(G); ...”.</p> <p>New Mexico needs to make the above change in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.200.</p>
3	20.3.7.708	20.1003	2002-2 2006-1	H&S	<p>Use of unsealed byproduct material for which a written directive is required</p> <p>New Mexico lists the wrong</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>references in 20.3.7.708.B(2). The cross references should be “in either subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 35.290, or Subsection H of 20.3.7.714 NMAC, incorporating 10 CFR 35.390, and Subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 290(c)(1)(ii)(G); ...”.</p> <p>New Mexico needs to make the above change in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.300.</p>
4	20.3.3.306	10 CFR 71 (multiple)	2004-1	NRC	<p>Compatibility With IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments</p> <p>New Mexico adopted 10 CFR 71 in its entirety in 20.3.3.306, including all sections reserved to NRC jurisdiction. New Mexico's regulations should not include sections designated Compatibility Category NRC as incorporated by reference</p> <p>New Mexico needs to add 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.101(c)(2), (d), and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125 to a list of items not incorporated by reference in 20.3.3.306 in order to meet the Compatibility Category NRC designation assigned to the above listed sections.</p>
5	20.3.4.467	10 CFR 20 Appendix E	2006-2 2006-3	C	<p>Nationally tracked sources threshold</p> <p>New Mexico has an error in the Ytterbium-169 line of their table. Column Category 2 terabecquerel should read “3” instead of “200” and column Category 2 curie should read “81” instead of “5,400”.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					New Mexico needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 20 Appendix E.
6	20.3.4.437 C	20.2008	2007-3	B	<p>Disposal of 11e.(3) and 11e.(4) byproduct material</p> <p>New Mexico states in 20.3.4.437.C "... as defined in paragraphs (3), (4), and (5) of the definition of byproduct material...". This should actually read "... as defined in paragraphs (2), (3), and (4) of the definition of byproduct material...". Also New Mexico omits an equivalent paragraph to 10 CFR 20.2008(b).</p> <p>New Mexico needs to make the above change and add a paragraph essentially identical to 20.2008(b) in order to meet the Compatibility Category B designation assigned to 10 CFR 20. 2008.</p>
7	20.3.3.302 C(4)	30.20(a)	2007-3	B	<p>Gas and aerosol detectors containing byproduct material</p> <p>New Mexico states in 20.3.3.302.C(4) "... with a specific license issued by the NRC or an agreement state, pursuant to 10 CFR 32.26 or comparable agreement state provision...". 10 CFR 32.26 is a Compatibility Category NRC and therefore would not have an equivalent agreement state provision. This section should read "... with a specific license issued by the NRC pursuant to 10 CFR 32.26, which authorizes ...".</p> <p>New Mexico needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 30.20(a).</p>
8	20.3.3.315 J	32.72	2007-3	B	<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs, containing byproduct material for</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>certain in vitro clinical or laboratory testing under general license</p> <p>New Mexico omits all other pharmacies from 20.3.3.315.J(2)(d)(ii) and 20.3.3.315.J(2)(f)(5). (NRC equivalent 10 CFR 32.72(b)(4)(ii) and (b)(5)(v)) This is a transboundary issue and therefore not compatible.</p> <p>New Mexico needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72.</p>
9	N/A	35.2	2007-3	H&S	<p>Definition: Positron Emission Tomography (PET) radionuclide production facility</p> <p>New Mexico omits the definition of Positron Emission Tomography radionuclide production facility from their regulations.</p> <p>New Mexico needs to add this definition in order to meet the Compatibility Category H&S assigned to 10 CFR 35.2 Definition Positron Emission Tomography radionuclide production facility.</p>

STATE REGULATION STATUS

State: New Mexico

Tracking Ticket Number: 8-57

[11 amendment(s) reviewed is identified by a ★

Date: June 25, 2008

at the beginning of the equivalent NRC requirement.]

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 09/15/1997	New Mexico 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	New Mexico 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 08/18/1997	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final	No Comments 09/15/1997	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995			New Mexico 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 07/14/2000	
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Not Applicable ¹	Not Applicable	New Mexico does not have any licensees subject to these regulations. (See SECY-95-112)

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1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable ¹	Not Applicable	New Mexico 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	Final	No Comments 07/14/2000	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	New Mexico 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 07/14/2000	
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 07/14/2000	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment	03/13/1998	Final	No Comments 07/14/2000	
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 07/14/2000	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superceded by 1997-5)	06/30/1998	Final ML021550112	No Comments 06/12/2002 ML021650055	New Mexico has adopted Final Regulations equivalent to RATS ID: 1997-5.
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final	No Comments 07/14/2000	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final	No Comments 07/14/2000	

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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	No Comments 07/14/2000	New Mexico 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 (Superceded by 2004-1)	04/01/1999	Final	No Comments 07/14/2000	New Mexico 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 07/14/2000	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final ML040640597	No Comments 03/11/2004 ML040760219	
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 ML052020072	No Comments 08/23/2005 ML052360017	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final	No Comments 07/14/2000	
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superceded 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 ML021550112	No Comments 06/12/2002 ML021650055	

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1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final ML040640597	No Comments 03/11/2004 ML040760219	
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 ML040640597	No Comments 03/11/2004 ML040760219	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150	02/12/2001	Final ML040640597	No Comments 03/11/2004 ML040760219	
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 (Superceded 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)
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final ML021550112	No Comments 06/12/2002 ML021650055	
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 ML040640597	No Comments 03/11/2004 ML040760219	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML040640597	No Comments 03/11/2004 ML040760219	
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	New Mexico does not have authority to regulate this material under its Agreement.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
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 ML052020072	No Comments 08/23/2005 ML052360017	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML052020072	No Comments 08/23/2005 ML052360017	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML052020072	No Comments 08/23/2005 ML052360017	
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material	02/16/2004	Final ML052020072	No Comments 08/23/2005 ML052360017	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML052020072	No Comments 08/23/2005 ML052360017	
★2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Proposed ML081350709	Comments 06/25/2008 ML081770231	
★2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Proposed ML081350709	No Comments 06/25/2008 ML081770231	Currently in place as a LC see NRC response letter ML072470593 dated 09/05/2007.
★2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Proposed ML081350709	Comments 06/25/2008 ML081770231	
★2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Proposed ML081350709	No Comments 06/25/2008 ML081770231	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
★2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35	04/29/2008	Proposed ML081350709	Comments 06/25/2008 ML081770231	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML080650711	No Comments 03/27/2008 ML080870430	New Mexico chose to revise its IC License Condition at the time of the Fingerprinting Order EA-07-305 License Condition Implementation. These were only minor editorial updates. The original license condition can be seen at ML053070159. The response letter sent 11/03/2005 can be seen at ML053080022
★2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Proposed ML081350709	Comments 06/25/2008 ML081770231	
★2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Proposed ML081350709	Comments 06/25/2008 ML081770231	
★2006-3	National Source Tracking System Part 20 71 FR 65865, 72 FR 59162	01/31/2009	Proposed ML081350709	Comments 06/25/2008 ML081770231	
★2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Proposed ML081350709	No Comments 06/25/2008 ML081770231	
★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 ML081350709	No Comments 06/25/2008 ML081770231	
★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 ML081350709	Comments 06/25/2008 ML081770231	
2007-4	Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305	06/05/2008	License Condition ML080650711	No Comments 03/27/2008 ML080870430	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
	72 FR 70901				
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011			

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