

July 10, 2008

Gary Butner, Branch Chief
Radiologic Health Branch
Division of Food, Drug, & Radiation Safety
CA Department of Health Services
P.O. Box 997414, MS-7610
Sacramento, CA 95899-7414

Dear Mr. Butner:

We have reviewed the proposed changes to the California regulations, Radiation Control Regulations, received by our office on July 1, 2008. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Part 71 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 Phillip Scott on July 9, 2008.

As a result of our review, we have four 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 California 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 California 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 California 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 by ADWhite for /

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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James G. Luehman, Deputy Director
 Division of Materials Safety and State Agreements
 Office of Federal and State Materials and
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Enclosures: As stated

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COMPATIBILITY COMMENTS ON CALIFORNIA PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	30373(a)	71.0(c)	2004-1	[B]	<p>Purpose and scope</p> <p>California lists this section as a section not incorporated by reference. According to California's rationale this section is covered by 30373(a). However 30373(a) is not essentially identical to 10 CFR 71.0(c). California needs to either change 30373(a) to be essentially identical to 71.0(c) or change 30373(a)(1) to say "10 CFR 71, section 71.0 through 71.3 except 71.0(c), ...".</p> <p>California needs to correct the above in order to meet the Compatibility Category [B] designation assigned to 10 CFR 71.0(c).</p>
2	30373(a)	71.3	2004-1	[B]	<p>Requirement for a license</p> <p>California lists this section as a section not incorporated by reference. According to California's rationale this section is covered by 30373(a). However 30373(a) is not essentially identical to 10 CFR 71.3. California needs to either change 30373(a) to be essentially identical to 71.3 or change 30373(a)(1) to say "10 CFR 71, section 71.0 through 71.2 except 71.0(c), ...".</p> <p>California needs to correct the above in order to meet the Compatibility Category [B] designation assigned to 10 CFR 71.3.</p>
3	30373(a)(1)	75.105(a), (c), & (d)	2004-1	C	<p>Quality Assurance Program</p> <p>California states in its rationale that 71.105(c) & (d) are Compatibility Category D and therefore does not incorporate them by reference. This is incorrect. They are actually a Compatibility Category C and should be incorporated by reference.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					California needs to remove 71.105(c) & (d) from 30373(a)(1) in order to meet the Compatibility Category C designation assigned to 10 CFR 71.105(a), (c), &(d).
4	30373(a)(1)	71.105(b)	2004-1	[C]	<p>Quality assurance program</p> <p>California states that 10 CFR 71.105(b) has the same essential objective as 71.103(b), and therefore they do not need to incorporate it by reference since they are already incorporating 71.103(b) by reference. However because the essential objectives of 71.103 are not the same as 71.105(b) California needs to remove 71.105(b) from its list of items not to be incorporated by reference.</p> <p>California needs to make the above change in order to meet the Compatibility Category [C] designation assigned to 10 CFR 71.105(b).</p>

STATE REGULATION STATUS

State: California

Tracking Ticket Number: 8-68

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

Date: July 10, 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	Not Required	Not Required	California 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	California 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 ML020030346	No Comments 03/18/2002 ML020780186	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final	No Comments 04/01/1998	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995			California 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.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30, 40 58 FR 39628	10/25/1996	Final ML022140223	Comments 08/22/2002 ML022350054	
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	License Condition ML051670371	No Comments 07/01/2005 ML051810407	
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable ¹	Not Applicable	California 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 04/01/1998	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	California 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			
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 11/16/1999	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment	03/13/1998	Final ML020030346	No Comments 03/18/2002 ML020780186	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final ML020030346	No Comments 03/18/2002 ML020780186	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superseded by 1997-5)	06/30/1998	Not Required	Not Required	California 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 ML020030346	No Comments 03/18/2002 ML020780186	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final	No Comments 04/01/1998	
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			California 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			California 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 ML020030346	No Comments 03/18/2002 ML020780186	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final ML020030346	No Comments 03/18/2002 ML020780186	
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 ML022140223	Comments 08/22/2002 ML022350054	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final ML020030346	No Comments 03/18/2002 ML020780186	
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 ML081160234	Comments 06/19/2008 ML081710246	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000			This regulation was previously reviewed and found acceptable (See NRC letter ML 020780186), however it was repealed on August 8, 2002, and CA is currently terminating licenses on a case by case basis
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 ML081080140	No Comments 05/13/2008 ML081340266	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71,	02/12/2001	Final ML060340073	No Comments 03/09/2006 ML060670437	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
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)
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final ML081160234	No Comments 06/19/2008 ML081710246	
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 ML020030346	No Comments 03/18/2002 ML020780186	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML020030346	No Comments 03/18/2002 ML020780186	
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	California 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 ML062210438	No Comments 08/31/2006 ML062490010	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML070920384	No Comments 04/23/2007 ML071140038	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML081160234 Final ML070920384 LC ML051580164 ML061790298	No Comments 06/19/2008 ML081710246 No Comments 04/23/2007 ML071140038 No Comments 07/18/2006 ML061990575	Part 34 Part 39 Part 36 adopted by reference
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct	02/16/2004	License Condition for 32.52 (a) & (b) ML040500440	No Comments 03/10/2004 ML040700191	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML062210438	No Comments 08/31/2006 ML062490010	
2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Final ML062210438	No Comments 08/31/2006 ML062490010	Partial submittal-only requirements of Part 20 reviewed. Parts 32 and 35 have not yet been reviewed.
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006			
★2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Proposed ML081840516	Comments 07/10/2008 ML081910792	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	License Condition ML062920179	No Comments 11/09/2006 ML063130004	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35	04/29/2008			
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML081280851	No Comments 05/13/2008 ML081340260	California chose to revise its IC License Condition at the time of the Fingerprinting Order EA-07-305 License Condition Implementation. The original license condition can be seen at ML053060120. The response letter sent 11/04/2005 can be seen at ML053080246.
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70	03/27/2009			
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	License Condition ML070360575	No Comments 02/16/2007 ML070470007	
2006-3	National Source Tracking System Part 20 71 FR 65865, 72 FR 59162	01/31/2009			
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010			
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			

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010			
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 ML081280851	No Comments 05/13/2008 ML081340260	
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 California does not have any licensees subject to these regulations during each review.