

February 14, 2011

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

Dear Mr. Butner:

We have reviewed the final revision to the California Radiation Control Regulations 30253, 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 Part 20 and the requirements of the seven amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Phillip Scott on February 9, 2011.

As a result of our review, we have 19 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. We have determined that if these regulations are revised, 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 you revise your regulations to address our comments, 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 location of any changes made by California, in response to our comments, 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 415-2320 ([kathleen.schneider@nrc.gov](mailto:kathleen.schneider@nrc.gov)) or Stephen Poy at 415-7135 ([stephen.poy@nrc.gov](mailto:stephen.poy@nrc.gov)).

Sincerely,

*/A.D. White for 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

COMPATIBILITY COMMENTS ON *CALIFORNIA* FINAL REGULATIONS

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	39.33	1998-5	C	<p><b>Radiation detection instruments</b></p> <p>State didn't submit an amendment to Part 39.</p> <p>CA did not submit their equivalent regulation to 39.33 for review.</p> <p>CA needs to provide for review above equivalent regulation in order to meet the Compatibility Category C designation 10 CFR 39.33.</p>
2	32.72	2006-1 2007-3	B	<p><b>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35</b></p> <p>California didn't submit amendment to Part 32.</p> <p>California did not submit their equivalent regulation to 32.72 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 32.72.</p>
3	32.74	2006-1	B	<p><b>Manufacture and distribution of sources or devices containing byproduct material for medical use</b></p> <p>California didn't submit amendment to Part 32.</p> <p>California did not submit their equivalent regulation to 32.74 for review.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 32.74.
4		30.3	2007-3	C	<p><b>Activities requiring license</b></p> <p>California didn't submit amendment to Part 30.</p> <p>California did not submit their equivalent regulation to 30.3 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category C designation 10 CFR 30.3.</p>
5		30.4	2007-3	C	<p><b>Definition: Consortium</b></p> <p>California didn't submit amendment to Part 30.</p> <p>California did not submit their equivalent regulation to 30.4 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category C designation 10 CFR 30.4.</p>
6		30.15	2007-3	B	<p><b>Certain items containing byproduct material</b></p> <p>California didn't submit amendment to Part 30.</p> <p>California did not submit their equivalent regulation to 30.15 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 30.15.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
7		30.18	2007-3	B	<p><b>Exempt quantities</b></p> <p>California didn't submit amendment to Part 30.</p> <p>California did not submit their equivalent regulation to 30.18 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 30.18.</p>
8		30.20	2007-3	B	<p><b>Gas and aerosol detectors containing byproduct material</b></p> <p>California didn't submit amendment to Part 30.</p> <p>California did not submit their equivalent regulation to 30.20 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 30.20.</p>
9		30.32	2007-3	B,C	<p><b>Application for specific licenses</b></p> <p>California didn't submit amendment to Part 30.</p> <p>California did not submit their equivalent regulation to 30.32 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B and C designation 10 CFR 30.32.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
10		30.34	2007-3	B,H&S	<p><b>Terms and conditions of licenses</b></p> <p>California didn't submit amendment to Part 30.</p> <p>California did not submit their equivalent regulation to 30.34 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B and H&amp;S designation 10 CFR 30.34.</p>
11		30.71	2007-3	B	<p><b>Schedule B</b></p> <p>California didn't submit amendment to Part 30.</p> <p>California did not submit their equivalent regulation to 30.71 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 30.71.</p>
12		30.72	2007-3	H&S	<p><b>Schedule C</b></p> <p>California didn't submit amendment to Part 30.</p> <p>California did not submit their equivalent regulation to 30.72 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category H&amp;S designation 10 CFR 30.72.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
13		31.5	2007-3	B	<p><b>Certain detecting, measuring, gauging, or controlling devices and/or an ionizing atmosphere</b></p> <p>California didn't submit amendment to Part 31.</p> <p>California did not submit their equivalent regulation to 31.5 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 31.5.</p>
14		31.12	2007-3	C	<p><b>General license for certain items and self-luminous products containing radium-226</b></p> <p>California didn't submit amendment to Part 31.</p> <p>California did not submit their equivalent regulation to 30.12 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category C designation 10 CFR 31.12.</p>
15		32.57	2007-3	B	<p><b>Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer</b></p> <p>California didn't submit amendment to Part 32.</p> <p>California did not submit their equivalent regulation to 32.57 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 32.57.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
16		32.58	2007-3	B	<p><b>Same: labeling of devices</b></p> <p>California didn't submit amendment to Part 32.</p> <p>California did not submit their equivalent regulation to 32.58 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 32.58.</p>
17		32.59	2007-3	B	<p><b>Same: Leak testing of each source</b></p> <p>California didn't submit amendment to Part 32.</p> <p>California did not submit their equivalent regulation to 32.59 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 32.59.</p>
18		32.71	2007-3	B	<p><b>Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license</b></p> <p>California didn't submit amendment to Part 32.</p> <p>California did not submit their equivalent regulation to 32.71 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 32.71.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
19		32.102	2007-3	B	<p><b>Schedule-C prototype tests for calibration or reference sources containing americium-241</b></p> <p>California didn't submit amendment to Part 32.</p> <p>California did not submit their equivalent regulation to 32.102 for review.</p> <p>California needs to provide for review above equivalent regulation in order to meet the Compatibility Category B designation 10 CFR 32.102.</p>



**STATE REGULATION STATUS**

State: California

Tracking Ticket Number: 10-58

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

Date: February 14, 2011

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 <b>(Superceded by 1997-5)</b>	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 <b>(Superceded by 1997-5)</b>	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 <b>(Superceded by 2002-2)</b>	01/27/1995	Final ML103050179	No Comments 01/05/2011 ML103340424	
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 ML022140223	Comments 08/22/2002 ML022350054	

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	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	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		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	
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		06/30/1998	Not Required	Not Required	California 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 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 <b>(Superseded by 2002-2 and 2005-2)</b>	10/20/1998	Final ML103050179  Final ML103550423	No Comments 01/05/2011 ML103340411  No Comments 02/14/2011 ML110120070	Part 35 only  Part 20 only
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 <b>(Superseded by 2004-1)</b>	04/01/1999	Final ML091240053	No Comments 06/11/2009 ML091470300	California has 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	
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 ML102160676	No Comments 09/28/2010 ML102300157	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
*1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final ML103050179  Final ML103550423	No Comments 01/05/2011 ML103340411  No Comments 02/14/2011 ML110120070	Part 35 only  Part 20 only
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 <b>(Superseded by 2004-1)</b>	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, 150 63 FR 1890; 63 FR 13773	02/12/2001	Final ML060340073	No Comments 03/09/2006 ML060670437	
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)

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 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 ML103050179  Final ML020030346  Final ML103550423  License Condition ML051580164 ML061790298	Comments 01/05/2011 ML103340411  No Comments 03/18/2002 ML020780186  No Comments 02/14/2011 ML110120070  No Comments 07/18/2006 ML061990575	Part 35 only  Part 20 and 35 prior to RATS ID: 2002-2.  Part 20 only  Part 36  Requirements of Part 39 have not yet been reviewed.
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		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 Material Parts 30, 31, 32 65 FR 79162	02/16/2004	Proposed ML102160676  License Condition for 32.52 (a) & (b) ML040500440	Comments 09/28/2010 ML102300157  No Comments 03/10/2004 ML040700191	Partial submittal-only requirements of Part 31 reviewed.
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 ML103050179  Final ML103550423	Comments 01/05/2011 ML103340411  Comments 02/14/2011 ML110120070	Part 35 only  Part 20 only  Requirements of Part 32 have not yet been reviewed.
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Final ML090210714	No Comments 02/06/2009 ML090260305	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML091240053	No Comments 06/11/2009 ML091470300	

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	Final ML103050179	Comments 01/05/2011 ML103340411	
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 71 FR 15005	03/27/2009	Final ML103050179 Final ML103550423	No Comments 01/05/2011 ML103340411 Comments 02/14/2011 ML110120070	Part 35 only.  Part 20 only  Requirements of Parts 32, 40 and 70 have not yet been
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 65685, 72 FR 59162	01/31/2009	Final ML103550423	No Comments 02/14/2011 ML110120070	
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Final ML103050179	Comments 01/05/2011 ML103340411	Part 35 only  Requirements of Part 32 have not been reviewed.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	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	Proposed ML102160676	No Comments 09/28/2010 ML102300157	Partial submittal-only requirements of Parts 31 and 150 reviewed.
*2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010	Final ML103050179  Final ML103550423	Comments 01/05/2011 ML103340411  Comments 02/14/2011 ML110120070	Part 35 only.  Part 20 only  Requirements of Part 30, 31, 32, 61 and 150 have not yet been reviewed.
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	Final ML103550423	No Comments 02/14/2011 ML110120070	
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012			

<sup>1</sup> IMPEP Team: verify that California does not have any licensees subject to these regulations during each review.