

UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20555-0001

July 19, 2019

Mr. Gonzalo L. Perez, Chief Radiologic Health Branch Division of Food, Drug & Radiation Safety California Department of Health Services P.O. Box 997414, MS-7610 Sacramento, CA 95899-7414

Dear Mr. Perez:

We have reviewed the California legally binding requirement, i.e., license condition for Title 10 of the *Code of Federal Regulations (10 CFR)*, Part 71 requirements, received by our office on July 10, 2019. These requirements were reviewed by comparison to the equivalent U.S. Nuclear Regulatory Commission (NRC) rules in 10 CFR Part 71, and Regulation Amendment Tracking System Identification Number (RATS ID) 2015-3 as identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the legally binding requirements with Phillip Scott on July 12, 2019.

As a result of our review, we have one comment that has been identified in the enclosure. Please note that we have limited our review to the legally binding requirements required for compatibility and/or health and safety. We have determined that if these requirements are revised, incorporating our comment and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements."

We request that when you revise your legally binding requirements to address our comment, a copy of the revised legally binding requirements be provided to us for review. As requested in NMSS 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, Security, State and Tribal Programs, NMSS.

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 NMSS State Communication Portal: <u>https://scp.nrc.gov/rulemaking.html</u>.

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 Michelle Beardsley, State Regulation Review Coordinator, at 301-415-2075 (michelle.beardsley@nrc.gov).

Sincerely,

/**RA**/

Kevin Williams, Deputy Director Division of Materials Safety, Security, State and Tribal Programs Office of Nuclear Material Safety and Safeguards

Enclosures:

- 1. Compatibility Comment
- 2. California SRS Data Sheet

SUBJECT: LETTER TO GONZALO PEREZ RE: CALIFORNIA LICENSE CONDITION DATE: July 19, 2019

DISTRIBUTION: SP[08] DIR RF (19-40) RErickson, RSAO CA File

ADAMS	*via email		
OFFICE	MSST	MSST	MSST
NAME	MBeardsley	PMichalak	KWilliams
DATE	7/12/19	7/19/19	7/19/19

OFFICIAL RECORD COPY

COMPATIBILITY COMMENT ON CALIFORNIA LEGALLY BINDING REQUIREMENTS

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1 License Condition 71.106(b) 2015-3 C Changes to Quality Assurance Program 1 License Condition 71.106(b) 2015-3 C Changes to Quality Assurance Program 1 License Condition In California's license cond appears that each revision Quality Assurance Program tied-down to the license by and revision number. How CFR 71.106(b) allows the assurance program approv change a previously approved, if the chanot reduce the commitmen previously approved quality assurance program. There revision number and date 1 in the license condition ma reflect any changes made approval holder in accorda CFR 71.106(b) after the ini was approved. California needs to revise to condition as indicated abor for revisions made by the C in accordance with 10 CFR in order to meet the Compu Category C designation as 10 CFR 71.106(b).	urance dition, it n to the am (QAP) is by the date wever, 10 e quality oval holder to oved quality ut prior hange does ents in the ity refore, the e tied-down ay not e by the QAP ance with 10 hitial QAP e their license ove to allow QAP holder R 71.106(b) patibility

STATE REGULATION STATUS

State: California

Tracking Ticket Number: 19-40 Date: 07/19/2019

[# amendment(s) reviewed identified by a * at	the
beginning of the equivalent NRC requirement.]	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	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 and 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	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.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30 and 40 58 FR 39628	10/25/1996	Final ML112970300	No Comments 01/20/2012 ML113330808	
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 ⁱ	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 and 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 and 70 59 FR 36026	08/15/1997	Final ML16034A230	Comments 05/24/16 ML16034A225	
1995-1	Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use Parts 30, 32 and 35 59 FR 61767; 59 FR 65243; 60 FR 322	01/01/1998	Final	No Comments 11/16/1999	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Final ML020030346	No Comments 03/18/2002 ML020780186	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20 and 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 (Superceded 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 and 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 and 70 60 FR 38235	11/24/1998	Final	No Comments 04/01/1998	
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20 and 35 60 FR 48623	10/20/1998	Final ML103050179	No Comments 01/05/2011 ML103340411	Part 35 only
	(Superceded by 2002-2 and 2005-2)		Final ML103550423	No Comments 02/14/2011 ML110120070	Part 20 only

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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 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 and 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 and 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 ML111740220	No Comments 08/24/2011 ML112130149	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20 and 35 62 FR 4120	05/29/2000	Final ML103050179	No Comments 01/05/2011 ML103340411	Part 35 only
			Final ML103550423	No Comments 02/14/2011 ML110120070	Part 20 only

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
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 and 150 62 FR 28947	06/27/2000	R ⁱⁱ ML14139A065 Final ML15012A519	Comments 08/06/2014 ML14139A060 No Comments 02/09/2015 ML15012A465	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40 and 70 62 FR 39057	08/20/2000	Final ML16034A230	Comments 05/24/16 ML16034A225	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 and 150 63 FR 1890; 63 FR 13773	02/12/2001	Final ML060340073	No Comments 03/09/2006 ML060670437	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40 and 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 ML081160234	No Comments 06/19/2008 ML081710246	
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 32, 35, 36 and 39 63 FR 39477; 63 FR 45393	10/26/2001	R ² ML14139A065 License Condition ML051580164 ML061790298 Final ML15012A519	No Comments 08/06/2014 ML14139A060 No Comments 07/18/2006 ML061990575 No Comments 02/09/2015 ML15012A465	Part 36
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	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
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	
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 and 39 65 FR 63750	01/08/2004	Final ML081160234	No Comments 06/19/2008 ML081710246	Part 34
			Final ML070920384	No Comments 04/23/2007 ML071140038	Part 39
			License Condition ML051580164 ML061790298	No Comments 07/18/2006 ML061990575	Part 36 adopted by reference

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31 and 32 65 FR 79162	02/16/2004	R ² ML14139A065 License Condition for 32.52 (a) & (b) ML040500440 Final ML15012A519	No Comments 08/06/2014 ML14139A060 No Comments 03/10/2004 ML040700191 No Comments 02/09/2015 ML15012A465	
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 and 35 67 FR 20249	10/24/2005	R ² ML14139A065 Final ML15012A516	No Comments 08/06/2014 ML14139A060 No Comments 02/09/2015 ML15012A465	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40 and 70 68 FR 57327	12/03/2006	Final ML090210714	No Comments 02/06/2009 ML090260305	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
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	
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 70 FR 16336; 71 FR 1926	04/29/2008	R ² ML14139A065 Final ML15012A519	No Comments 08/06/2014 ML14139A060 No Comments 02/09/2015 ML15012A465	
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.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	R ² ML14139A065 Final ML15012A519	No Comments 08/06/2014 ML14139A060 No Comments 02/09/2015 ML15012A465	Note: changes to Part 40 and 70 are not required for compatibility.
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	R ² ML14139A065 Final ML15012A519	No Comments 08/06/2014 ML14139A060 No Comments 02/09/2015 ML15012A465	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32 and 150 72 FR 58473	12/17/2010	R ² ML14139A065 Final ML15012A519	No Comments 08/06/2014 ML14139A060 No Comments 02/09/2015 ML15012A465	
2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61 and 150 72 FR 55864	11/30/2010	R ² ML14139A065 Final ML15012A519	No Comments 08/06/2014 ML14139A060 No Comments 02/09/2015 ML15012A465	
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 and 20 72 FR 68043	02/15/2011	Final ML103550423	No Comments 02/14/2011 ML110120070	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35	09/28/2012	Proposed ML14139A0652	No Comments 08/06/2014 ML14139A060	
	74 FR 33901		Final ML15012A519	No Comments 02/09/2015 ML15012A465	
2011-1	Decommissioning Planning Parts 20, 30, 40 and 70 76 FR 35512	12/17/2015	Proposed ML18067A028	No Comments 04/13/2018 ML18067A027	
			Final ML19066A324	No Comments 03/28/2019 ML19066A318	
2011-2	Licenses, Certifications, and Approvals for Materials Licensees Parts 30, 36, 39, 40, 70 and 150 76 FR 56951	11/14/2014	Final ML13144A735	No Comments 07/03/2013 ML13162A553	
			License Condition ML13196A091	No Comments 08/21/2013 ML13196A080	Part 36 adopted by reference
2012-1	Change of Compatibility of Parts 31.5 and 31.6 (See RATS ID: 2001-1 for Rule text) 77 FR 3640	01/25/2015	R ² ML14139A0652	No Comments 08/06/2014 ML14139A060	
			Final ML15012A519	No Comments 02/09/2015 ML15012A465	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2012-2	Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste Part 71 77 FR 34194	08/10/2015	Proposed ML18065B098	No Comments 04/19/2018 ML18065B082	
2012-3	Technical Corrections Parts 30, 34, 40 and 71 77 FR 39899	08/06/2015	Proposed ML18065B098	No Comments 04/19/2018 ML18065B082	
2012-4	Requirements for Distribution of Byproduct Material Parts 30, 31, 32, 40 and 70 77 FR 43666	10/23/2015	Proposed ML14139A0652 Final	No Comments 08/06/2014 ML14139A060 No Comments	
			ML15012A519	02/09/2015 ML15012A465	
2013-1	Physical Protection of Byproduct Material, 10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39 and 71 78 FR 16922	03/19/2016	Proposed License Condition ML15216A474	Comments 08/31/2015 ML15216A443	Part 37 only.
			Revised License Condition ML15281A285	No Comments 11/03/2015 ML15281A277	Part 37 only.
			Proposed ML18065B098	Comments 04/19/2018 ML18065B082	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2013-2	Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions, Parts 30, 40 and 70 78 FR 32310	08/27/2016	Proposed ML19015A163 Revised Proposed ML19100A330	Comments 01/28/2019 ML19015A145 No Comments 04/15/2019 ML19100A318	
2015-1	Domestic Licensing of Special Nuclear Material – Written Reports and Clarifying Amendments Part 70 79 FR 57721, 80 FR 143	01/26/2018	Proposed ML18065B098	No Comments 04/19/2018 ML18065B082	
2015-2	Safeguards Information - Modified Handling Categorization, Change for Materials Facilities Parts 30, 37, 73 and 150 79 FR 58664, 80 FR 3865	01/28/2018	Proposed ML15216A474 Revised License Condition ML15281A285 Proposed ML18065B098 Revised Proposed ML18324A655	No Comments 08/31/2015 ML15216A443 No Comments 11/03/2015 ML15281A277 No Comments 04/19/2018 ML18065B082 No Comments 01/03/2019 ML18324A651	Revised License Condition ML15281A285

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
<mark>*2015-3</mark>	Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements Part 71	07/13/2018 *extended to 08/15/2020 See STC 17-060	Proposed ML18065B098	Comments 04/19/2018 ML18065B082	
	80 FR 33987		Revised Proposed ML18324A655	No Comments 01/03/2019 ML18324A651	
			License Condition ML19193A047	Comment 07/19/2019 ML19193A045	The LC contained requirements for 10 CFR 71.101(c) and 71.106(b) only.
2015-4	Miscellaneous Corrections, Parts 37 and 40 80 FR 45841	09/02/2018	Proposed ML18065B098	Comments 04/19/2018 ML18065B082	
			Revised Proposed ML18324A655	No Comments 01/03/2019 ML18324A651	
2015-5	Miscellaneous Corrections, Parts 19, 20, 30, 32, 37, 40, 61, 70, 71 and 150 80 FR 74974	12/31/2018	Proposed ML18065B098	No Comments 04/19/2018 ML18065B082	
			Revised Proposed ML18324A655	No Comments 01/03/2019 ML18324A651	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2018-1	Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments, 10 CFR Parts 30, 32 and 35	01/14/2022			
2018-2	Miscellaneous Corrections – Organizational Changes 10 CFR Parts 37, 40. 70 and 71	12/21/2021			
N/A	Parts 35.13, 35.14, 35.24, 35.27, 35.57 and 35.2024		License Condition ML111400455	No Comments 07/11/2011 ML111740678	

ⁱ IMPEP Team: verify that California does not have any licensees subject to these regulations during each review. ⁱⁱ R stands for revisions to final rule.