

September 29, 2004

Mr. Edgar D. Bailey, C.H.P., Chief
Radiologic Health Branch
Division of Food, Drug & Radiation Safety
California Department of Health Services
P. O. Box 942732
Sacramento, CA 94234-7320

Dear Mr. Bailey:

We have reviewed the California license conditions that were submitted to meet the Industrial Radiography Two-Person Rule, 10 CFR 34.41 (a) and the Report and Notification of a Medical Event, 10 CFR 35.3045. Our review and comments are in response to the State's request for Nuclear Regulatory Commission (NRC) evaluation of the license conditions submitted by the State on September 1, 2004. These license conditions were reviewed by comparison to the equivalent NRC rules in 10 CFR 34.41 and 10 CFR 35.3045. We discussed our review of the license conditions with you on September 28, 2004.

As a result of our review, we found that neither of the license conditions are adequate to meet the compatibility requirements as established in the Office of State and Tribal Programs (STP) Procedure SA-200. Please note that we have limited our review to the California license conditions required for compatibility and/or health and safety. The enclosed chart lists the comments as found during the review of the submitted license conditions. If there are any comments which the State believes are in error, the State should identify the section of their regulations that meet the designated compatibility category and submit them to the NRC for review. If the State desires to meet these requirements by license condition, it is suggested if State law allows, that the State reference 10 CFR 35.3045 and 10 CFR 34.41 directly or include the exact CFR text as written in these sections.

The SRS Data Sheet summarizes our knowledge of the status of other California regulations or license conditions, 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 STP website: <http://www.hrsd.ornl.gov/nrc/rulemaking.htm>.

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 me, or John Zabko of my staff at (301)415-2308 or JGZ@NRC.GOV.

Sincerely,

Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

COMPATIBILITY COMMENTS ON CALIFORNIA LICENCE CONDITIONS

STATE SECTION	NRC SECTION	CATEGORY	SUBJECT and COMMENTS
<p>1 Submitted License Condition Radiography Two-Person Rule</p>	<p>34.41 (a)</p>	<p>B</p>	<p>Conducting Industrial Radiographic Operations</p> <p>The California license condition requires that radiographers must meet the requirements as stated in 17 CCR 30333(b). This regulation lacks the requirements as stated in 10 CFR 34.41, that requires the radiographer assistant to meet the training requirements in CFR 34.43 (C). In specific, the license condition (and referenced CA rule text) omits the requirements of a written and practical examination as stated in 10CFR CFR 34.43 (C)(3)</p> <p>The State needs to include the requirements as stated in 10 CFR 34.43 (C)(3) to meet compatibility.</p>
<p>2 Submitted License Condition</p>	<p>Old Part 35.2 Definitions and 35.3045</p>	<p>C</p>	<p>Old Part 35 Definitions: Medical Misadministration</p> <p>The license condition does not include all of the requirements of this section, i.e. the requirements for the reporting of a misadministration. If it was the State's intent to just list the I-131 reporting threshold, the license condition does reflect that, and is compatible in that respect only. However, the license condition, and the referenced California rule section 17 CCR 30322 does not meet the compatibility requirements for 10 CFR 35.2 for the definition of misadministration. Two examples of missing requirements are: the I-125 reporting limit and the dose percentage limit for reporting.</p> <p>In addition, it is noted, that this license condition references the old Part 35 requirements that preceded the 10 CFR 35 change in April 2002. The State should be aware that citing the old Part 35 text will only be valid until the date for Agreement State adoption of the new Part 35 medical amendments are required, October 24, 2005, at which point this rule text will no longer be compatible.</p> <p>To achieve adequacy and compatibility the State needs to add language to its rules or license condition to meet the requirements for the reporting of medical misadministrations as stated in 10 CFR 35.2 (Old Rule) or 10 CFR 35.3045 (New Rule) . If the State already has language in rules that meets the requirements of these sections they are requested to submit the sections for review.</p>

STATE REGULATION STATUS

State: California

Tracking Ticket Number: 4-252

[No amendments reviewed]

Date: September 29, 2004

NRC Chronology Identification	FR Notice (Date Due For State Implementation)	RATS ID	Proposed (P) / Final (F) ¹ Rule / ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F ML022140223	Y 8/22/02 ML022350054	
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required 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; (1/1/94)	1991-3	F ML020030346	Y 3/18/02 ML020780186	11/14/01
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F	N 4/1/99	9/9/97
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1			
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions- Parts 30,35	57 FR 45566; (none)	1992-2			Not required ³
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1	F ML022140223	Y 8/22/02 ML022350054	
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not applicable SECY-95- 112 ⁴
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618; (none)	1994-1	F	N 4/1/98	9/9/97 Not required ³
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3			
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; (1/1/98)	1995-1	F	N 11/16/99	11/12/99
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F ML020030346	N 3/18/02 ML020780186	11/14/01
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983; (3/1/98)	1995-3	F ML020030346	N 3/18/02 ML020780186	11/14/01
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4			
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F ML020030346	N 3/18/02 ML020780186	11/14/01

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Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F	N 4/1/98	9/9/97
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7			
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724; (4/1/99)	1996-1			
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses- Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required ³
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F ML020030346	N 3/18/02 ML020780186	11/14/01
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act- Part 20	61 FR 65120; (1/9/00)	1997-1	F ML020030346	N 3/18/02 ML020780186	11/14/01
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2	F ML022140223	Y 8/22/02 ML022350054	
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F ML020030346	N 3/18/02 ML020780186	11/14/01
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5			
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F ML020030346	N 3/18/02 ML020780186	11/14/01
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea- Part 30	62 FR 63634; (1/02/01)	1997-7			
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1			
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required ³
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4			
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393; (10/26/01)	1998-5	F ML020030346	N 3/18/02 ML020780186	11/14/01
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F ML020030346	N 3/18/02 ML020780186	11/14/01

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Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			Not required ³
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524; (2/2/03)	1999-3			
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1			
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2			
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F license conditions 32.52 (a) & (B)	N 3/10/04 ML040700191	license conditions only for 32.52 (a) & (B) 02/25/04
Revision of the Skin Dose Limit-Part 20	67 FR 16298; (4/5/05)	2002-1			
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (10/24/05)	2002-2			
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327; (12/3/06)	2003-1			
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1			

Edgar D. Bailey

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September 29, 2004

Mr. Edgar D. Bailey, C.H.P., Chief
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Sincerely,

Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures:
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Sincerely,

IRA By K.N. Schneider For

Josephine M. Piccone, Deputy Director
 Office of State and Tribal Programs

Enclosures: As stated

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COMPATIBILITY COMMENTS ON CALIFORNIA LICENCE CONDITIONS

STATE SECTION	NRC SECTION	CATEGORY	SUBJECT and COMMENTS
1 Submitted License Condition Radiography Two-Person Rule	34.41 (a)	B	<p>Conducting Industrial Radiographic Operations</p> <p>The California license condition requires that radiographers must meet the requirements as stated in 17 CCR 30333(b). This regulation lacks the requirements as stated in 10 CFR 34.41, that requires the radiographer assistant to meet the training requirements in CFR 34.43 (C). In specific, the license condition (and referenced CA rule text) omits the requirements of a written and practical examination as stated in 10CFR CFR 34.43 (C)(3)</p> <p>The State needs to include the requirements as stated in 10 CFR 34.43 (C)(3) to meet compatibility.</p>
2 Submitted License Condition	Old Part 35.2 Definitions and 35.3045	C	<p>Old Part 35 Definitions: Medical Misadministration</p> <p>The license condition does not include all of the requirements of this section, i.e. the requirements for the reporting of a misadministration. If it was the State's intent to just list the I-131 reporting threshold, the license condition does reflect that, and is compatible in that respect only. However, the license condition, and the referenced California rule section 17 CCR 30322 does not meet the compatibility requirements for 10 CFR 35.2 for the definition of misadministration. Two examples of missing requirements are: the I-125 reporting limit and the dose percentage limit for reporting.</p> <p>In addition, it is noted, that this license condition references the old Part 35 requirements that preceded the 10 CFR 35 change in April 2002. The State should be aware that citing the old Part 35 text will only be valid until the date for Agreement State adoption of the new Part 35 medical amendments are required, October 24, 2005, at which point this rule text will no longer be compatible.</p> <p>To achieve adequacy and compatibility the State needs to add language to its rules or license condition to meet the requirements for the reporting of medical misadministrations as stated in 10 CFR 35.2 (Old Rule) or 10 CFR 35.3045 (New Rule) . If the State already has language in rules that meets the requirements of these sections they are requested to submit the sections for review.</p>

STATE REGULATION STATUS

State: California

Tracking Ticket Number: 4-252

[No amendments reviewed]

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ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required ³
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Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F	N 4/1/99	9/9/97
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Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not applicable SECY-95- 112 ⁴
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618; (none)	1994-1	F	N 4/1/98	9/9/97 Not required ³
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Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3			
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; (1/1/98)	1995-1	F	N 11/16/99	11/12/99
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F ML020030346	N 3/18/02 ML020780186	11/14/01
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983; (3/1/98)	1995-3	F ML020030346	N 3/18/02 ML020780186	11/14/01
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Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F ML020030346	N 3/18/02 ML020780186	11/14/01

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Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7			
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724; (4/1/99)	1996-1			
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses- Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required ³
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F ML020030346	N 3/18/02 ML020780186	11/14/01
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act- Part 20	61 FR 65120; (1/9/00)	1997-1	F ML020030346	N 3/18/02 ML020780186	11/14/01
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Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea- Part 30	62 FR 63634; (1/02/01)	1997-7			
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1			
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required ³
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4			
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393; (10/26/01)	1998-5	F ML020030346	N 3/18/02 ML020780186	11/14/01
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F ML020030346	N 3/18/02 ML020780186	11/14/01

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New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2			
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F license conditions 32.52 (a) & (B)	N 3/10/04 ML040700191	license conditions only for 32.52 (a) & (B) 02/25/04
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Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1			

1. Or other generic Legally Binding Requirements.
2. (Y/N) Y means “Yes,” there are comments in the review letter that the State needs to address.
N means “No,” there are no comments in the review letter.
3. Not required means these regulations are not required for purposes of compatibility.
4. Or other generic Legally Binding Requirements.
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