

June 19, 2006

Gary Butner, Acting Chief
Radiologic Health Branch
MS 7610
PO Box 997414
Sacramento, CA 95899-7414

Dear Mr. Butner:

The Office of State and Tribal Programs (STP) has reviewed your letter dated May 4, 2006. This letter was a response to our letter dated February 16, 2006, which transmitted our comments on California's proposed regulation addressing 10 CFR 30.21, "Radioactive Drug: Capsules Containing Carbon-14 Urea for In Vivo Diagnostic Use for Humans". We discussed our review of the regulations with Phillip Scott on June 16, 2006.

The additional information provided in your letter has enabled us to verify that your regulations meet the essential objectives of the Compatibility Category B designation assigned to 10 CFR Part 30.21. As a result of our review, we have no comments. Please note that we have limited our review to regulations required for compatibility and/or health and safety. We have determined that the regulations, as proposed, meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) 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 STP Procedure [SA-201](#), "Review of State Regulatory Requirements," please highlight any final changes and provide a copy to STP.

The SRS Data Sheet summarizes our knowledge of other California regulations. 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 Web Site: <http://www.hsr.gov/nrc/rulemaking.htm>.

If you have any questions regarding the review, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, or Mr. Osiris Siurano of my staff at (301)415-2307 or e-mail: OSP@NRC.GOV.

Sincerely,

IRA By KNSchneider For

Dennis K. Rathbun, Deputy Director
Office of State and Tribal Programs

Enclosure:
As stated

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IRA By KNSchneider For

Dennis K. Rathbun, Deputy Director
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Enclosure: As stated

Sunsi Review Complete

- Publicly Available Non-Publicly Available
- Non-Sensitive Sensitive

Distribution:

DIR RF [6-133] DCD (SP08) PDR (YES✓)
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OFFICE	STP	STP	OGC	STP:DD
NAME	OSiurano	KNSchneider	STreby	KSchneider for DRathbun
DATE	06/02/06*	06/02/06*	06/08/06*	06/08/06*

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STATE REGULATION STATUS

State: California

Tracking Ticket Number: 6-133

[1 amendment reviewed is identified

Date: 06/19/2006

by a ★ at the beginning of each equivalent NRC regulation]

NRC Chronology Identification	FR Notice (Date Due For State Implementation)	RATS ID	Proposed (P) / Final (F) ¹ Rule / License Condition (LC) 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	P ML051670371	N 10/13/05 ML052870320	Partial Submittal-only requirements of Part 34 reviewed
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	N 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 4/1/98	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	LC ML051580164	N 6/30/05 ML051810407	
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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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	P ML051580164	N 6/30/05 ML051810453	
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
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

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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	P ML051670371	Y 10/13/05 ML052870320	
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	P ML060250530 05/04/06 - ML061360365	Y 02/16/06 ML060550003 N 06/19/06 ML061700392	
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1	F ML060340073	N 3/9/06 ML060670437	
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	63 FR 37059;	1998-4	P	Y 10/13/05	

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Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	(7/9/01)		ML051670371	ML052870320	
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
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	P ML060100445	N 1/30/06 ML060300393	
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	P ML053530133	Y 1/17/06 ML060170651	Partial Submittal - Only requirements of Part 39 reviewed
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	P ML053530133 P ML051580164	Y 1/17/06 ML060170651 N 6/30/05 ML051810453	Partial Submittal - Only requirements of Part 39 reviewed (P 12/22/05) Partial Submittal - only requirements of Part 34 reviewed (PN 6/30/05)
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	LC for 32.52 (a) & (b) ML003696531	N 3/10/04 ML040500440	02/25/04

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Revision of the Skin Dose Limit-Part 20	67 FR 16298; (4/5/05)	2002-1	P ML060100445	N 1/30/06 ML060300393	Partial submittal-only requirements of Part 20 reviewed (1/ /06)
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (10/24/05)	2002-2	P ML060100445	N 1/30/06 ML060300393	Partial submittal-only requirements of Part 20 reviewed (1/30/06)
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			
Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1			
Medical Use of Byproduct Material - Recognition of Speciality Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2			
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) ⁷	70 FR 72128; (12/1/05)	2005-3	LC ML053060120	N 11/04/05 ML053080246	

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. A State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. See: “Final Policy Statement on Adequacy and Compatibility of Agreement State Programs,” III.1. Time Frame for Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
5. ADAMS ML Number
6. By letter dated September 2, 2005, from Paul H. Lohaus, Director, Office of State and Tribal Programs, Agreement States were given 90 days to issue legally binding requirements satisfying the requirements of NRC Order EA-05-090.