

NOV 16 1999

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 final California regulation §30210.2, Labeling Requirements for the Manufacture, Preparation or Transfer for Commercial Distribution of Drugs Containing Radioactive Material for Human Use as Authorized by a Specific License, (R-12-98), with a November 12, 1999 effective date. The request was based on your October 19, 1999 letter. The final regulation is in response to the one amendment identified in the enclosed Regulation Assessment Tracking System (RATS) Data Sheet. The regulations were reviewed by comparison to the equivalent NRC regulation in 10 CFR Part 32.72. In addition, we reviewed our July 19, 1999 letter to you that addressed the proposed regulation.

As a result of the NRC review, we have determined that the California regulation, as adopted, meets the compatibility and health and safety categories established in the Office of State Programs (OSP) Procedure SA-200.

We have also summarized on the RATS Data Sheet our knowledge of the status of other California regulations. Please let us know if you note any inaccuracies or have any comments on the information contained in the RATS Data Sheet.

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 at (301) 415-2325 or Linda McLean at (817) 860-8116 or e-mail: mlm1@nrc.gov.

Sincerely,

Original signed by:  
Frederick C. Combs, Deputy Director  
Office of State Programs

Enclosure:  
As stated

Distribution:

DIR RF (9-230)  
PHLohaus  
SDroggitis  
DChamberlain, RIV  
RBlanton/ASPO  
BUSilton  
California File

DCD (SP08)  
PDR (YES✓)

\*See previous concurrence.

**DOCUMENT NAME:G:\SNS\CA FINAL REG REVIEW 99.WPD**

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OFFICE	RIV:SAO	OSP	OGC	OSP:DD				
NAME	MLMcLean:kk/gd	SNSalomon	SATreby	FCCombs				
DATE	10/28/99*	11/08/99*	11/12/99*	11/9/99				

OSP FILE CODE: SP-AG-4

PDR STPRG

NRC FILE CENTER COPY 8

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NAME	MLMcLean:kk/gd	SNSalomon	SATreby SM	FCCombs
DATE	10/28/99*	11/08/99*	11/12/99	11/9/99

*no legal objection.*

OSP FILE CODE: SP-AG-4

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OFFICE	RIV:SAO ML <sup>via</sup> <input checked="" type="checkbox"/> E	OSP	<input checked="" type="checkbox"/> E	OGC		OSP:DD			
NAME	MLMcLean:kk <sup>F-mail</sup>	SNSalomon <sup>SNS</sup>	SATreby	FCCombs					
DATE	10/23/99 <sup>515</sup>	11/8/99	11/ /99	11/ /99					

OSP FILE CODE: SP-AG-4



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

November 16, 1999

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Sincerely,

A handwritten signature in black ink, appearing to read "F. Combs", with a long horizontal line extending to the right.

Frederick C. Combs, Deputy Director  
Office of State Programs

Enclosure:  
As stated

**REGULATION ASSESSMENT TRACKING SYSTEM  
RATS DATA SHEET**

State: California

Tracking Ticket Number: 9-230

[One final amendment (11/12/99) identified by ★]

Date: November 16, 1999

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed/ Final-Comment (Y/N) <sup>1</sup>	NRC Review Date	Final State Regulation (Effective Date)
Standards for Protection Against Radiation-Part 20	56 FR 23360 plus others (1/1/94)	1991-3	F-N	10/25/97	3/3/94
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843 (1/10/94)	1991-1	P-N	7/24/97	
ASNT Certification of Radiographers-Part 34	56 FR 11504 (none)	1991-2			Not required <sup>2</sup>
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
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			
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628 (10/25/96)	1993-1	P-N	5/7/97	
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	Not required 9/9/97
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220 (7/1/97)	1994-2			Not required
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			

<b>NRC Chronology Identification</b>	<b>FR Notice (State Due Date)</b>	<b>RATS ID</b>	<b>Proposed/ Final-Comment (Y/N)<sup>1</sup></b>	<b>NRC Review Date</b>	<b>Final State Regulation (Effective Date)</b>
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649 60 FR 25983 (3/1/98)	1995-3			
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			
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
Termination or Transfer of Licensed Activities: Recordkeeping Requirements- Parts 20, 30, 40, 61, 70	61 FR 24669 (6/17/99)	1996-3			
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65119 (1/9/00)	1997-1			
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907 (none)	1997-4			Not required
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			
Criteria for the Release of Individuals Administered Radioactive Material- Parts 20, 35	62 FR 4120 (5/29/00)	1997-3			
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28948 (6/27/00)	1997-5			
Radiological Criteria for License Termination- Parts 20, 30, 40, 70	62 FR 39057 (8/20/00)	1997-6			
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634 (1/02/01)	1997-7			

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Deliberate Misconduct by Unlicensed Persons- Parts 30, 40, 61, 70, 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
License Term for Medical Use Licenses-Part 35	63 FR 31604 (none)	1998-3			Not required
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 39347 63 FR 45393 (10/26/01)	1998-5			
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127 (11/20/01)	1998-6			
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506 (6/11/02)	1999-1			

1. (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.
2. Not required means these regulations are not required for purposes of compatibility.

# STATE PROGRAMS OFFICE TRACKING SYSTEM

## ACTIVE PROJECTS

Date: 10/27/99

Project ID: 9-230

Project Description: REVIEW OF CALIFORNIA FINAL STATE REGULATION - 1995-1

StartDate: 10/27/99

Original Date: 12/1/99

Project Lead: MCLEAN

Completion Date:

Due Date: 12/1/99

Status: LTR TO FRED COMBS FROM EDGAR BAILEY.

Requester/Office: EDGARD BAILEY/CALIFORNIA

Extension Requested:

Extension Date:

RITS Code:

PA No: