

State of California—Health and Human Services Agency

Department of Health Services



July 7, 2005

Mr. Paul Lohaus Office of State and Tribal Programs U.S. Nuclear Regulatory Commission Mail Stop 0-3-C-10 Washington, DC 20555

Dear Mr. Lohaus:

The California Department of Health Services (DHS) strongly supports conducting a comprehensive radiologic health program in California. DHS management and the Radiologic Health Branch (RHB) staff have worked together to address the recommendations identified in the Integrated Materials Performance Evaluation Program (IMPEP) review in April 2004. We would like to report that the number one recommendation required DHS to ensure adequate funding for RHB activities. On June 22, 2005, emergency fee regulations were approved by the State. These fees will provide adequate resources to conduct the radiation control program activities for the State.

A summary of the current status of the ten recommendations identified during the IMPEP is enclosed. We have completed six of the objectives and are working to complete final tasks in the outstanding objectives. During our upcoming conference call, we would like to discuss our proposed milestones and anticipated completion dates in order to ensure that we are adequately responding to the U.S. Nuclear Regulatory Commission's concerns. We look forward to discussing our progress with you.

Sincerely,

Larry Barrett, DVM, MS, DACVPM, Chief Division of Food, Drug, and Radiation Safety

Enclosure

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item			NRC Due	Approved by	Completion Date	Otatus	Completion
		Synopsis	Date	RHB		Status	Date
		Increases fees charged by RHB	N/A		November	Regs Effective! Emergency	June 2005
	through Emergency Rulemaking				2005	Rulemaking underway.	
	Process (R-	20					
1	3-04E)						
	Industrial Radiography Certification	Requires certification for radiographers using RAM and	06/30/2002	Feb 05	July 2006	Under DHS-Budget Review.	
		X-ray sources. Addresses 4 NRC changes including				·	
		the 2-person rule.				,	
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2	NIDC Hadatas	Addresses NDC changes for CLD's and register-tion	Various	July 05	June 2006	Reviewed by DHS-Office of	
	NRC Updates (R-7-04)	Addresses NRC changes for GLD's and registration.	dates in	July 05	Julie 2000	Regulations. Package being revised.	[
3	(R-7-04)		past			regulations. Fackage being revised.	
	Molt Logging	electron compensation sources, sealed source	Various	July 05	June 2006	Reviewed by DHS-Office of	
		performance criteria and tritium neutron generator	dates in	July 05		Regulations. Package being revised.	-
	(R-10-04)	sources.	past			i	
		Sources.	Past				
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	Deliberate Misconduct	Addresses NRC adoption of a misconduct rule for	2/12/2001	Dec 04	December	DHS approved, sent to Agency.	
		unlicensed persons.		<u> </u>	2005		
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5	· · · · · ·						
	Standards for Protection Against	Updates 10 CFR 20 incorporation date from 1999 to	Various	May 05	July 2006	Reviewed by DHS-Office of	
		2005.	dates in			Regulations. Package being revised.	-
	(R-05-007)		past	1			
6							
	Exempt Radioactive Products	Addresses NRC's 1uCi C-14 product exemption.	1/2/2001		August 2006	Carved from R-7-04. In revision.	
	(R-05-008)] -		
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	Nuclear Medicine licensing	Addresses NRC changes to Part 35	4/24/2005 &	1	December	Package under development. This	
	•]	dates in		2006	package complex. NRC continues to	
_ ا			past			propose changes and address new	
8	=:		40/0/0000	 		netitions for rulemaking. May affect	
	Financial Assurance	Addresses financial surety dollar amounts.	12/3/2006		March 2007	Package under development	
9							
- "	Transportation	Addresses part 71 and 49 CFR.	10/1/2007	 	January 2007	Package under development	-
	Transportation	Andresses part / I and 45 OFM.	10, 1,200,		January 2007	i ackage under development	
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Updated: 7/7/2005

	Recommendation	Task	Milestones	Assigned To	Anticipated Completion Date	Status	Actual Completion Date
1.	The review team recommends that the State ensure that adequate resources, both funding and staffing, be devoted to the radiation control program.	Increase funding to adequately support program activities.	Develop emergency regulations to increase funding to adequately support program activities.	Reilly /Barrett	May 2005	Obtained Department, Agency, and Governor's approval to increase fees by emergency regulation to adequately support program activities. Emergency fee regulations effective June 22, 2005	June 05
		Identify staff shortages and obtain adequate staff.	 (1) Develop proposal to establish nine additional staff in Governor's 05-06 Budget. (2) Conduct hiring exams for all RHB classifications by April 2005. (3) Conduct hiring interviews and complete hiring for 95% of vacant positions. 	Bailey/ Butner	August 2005	(1) RHB received approval for an additional 9 positions when the Governor's Budget is signed. (2) Hiring exams were completed June 2005 for the RHB Health Physicist classification. (3) RHB is currently in the process of conducting hiring interviews for new staff. Ninety-five percent of all supervisory positions have been filled.	
2.	The review team recommends that the Branch enhance its ability to account for the whereabouts and security of licensed materials known to have existed under a license.	Identify location of licensed materials known to have existed under a license.	Complete investigation of lost licensees within 90 days.	Anderson /Butner	Dec. 2005	Investigations into lost licenses were conducted within 90 days. Currently, three licenses are still lost and investigations are still underway. The licensed sources are 2 gauges, and a Radiflow unit.	
		Develop procedures to ensure that the location and security of licensed materials are routinely monitored to prevent loss.	Report to Branch management if licensed materials are not located within 30 days using new procedures.	Anderson/ Butner	August 2005	Procedures have been developed to identify and track lost licensees and staff training is being conducted.	June 2005
3	The review team recommends that the Branch implement procedures to ensure inspection findings are issued to licensees within 30 days of the completion of routine inspections.	Identify inspection findings that have not been issued to licensees within 30 days.	Complete identification of inspection findings that have not been issued to licensees within 60 days.	Anderson/ Butner	August 2004	Identification of inspection findings that have not been issued to licensees has been completed.	August 2004

Recommendation	Task	Milestones	Assigned To	Anticipated Completion Date	Status	Actual Completion Date
	Develop new procedures to monitor inspection findings and ensure they are issued within 30 days.	Report to Branch management if inspection findings are not issued within 30 days using new procedures.		November 2004	Procedures have been developed and implemented to monitor inspection findings and ensure they are issued to licensees within 30 days.	November 2004
The review team recommends that the incident and allegation history of a licensee be reviewed during evaluation of licensing actions.	Develop procedures and appropriate information technology enhancements to automatically review incident and allegation history during licensing actions.	Complete new searchable database to automatically review 100% of incident and allegation history during licensing actions.	Butner/ Perez	March 2005	New information technology enhancements were made to the database system to allow the review of 100% of incident and allegation histories during licensing actions. This task is complete.	June 2005
The review team recommends RHB, in coordination with INEEL, complete and close all reportable incidents in NMED.	Identify reportable incidents that have not been closed in NMED.	Identify all outstanding reportable incidents that have not been closed in NMED within 60 days of IMPEP.	Anderson/ Butner	August 2004	RHB identified nearly 400 open incident reports that needed to be completed and closed.	August 2004
	Develop new procedures to monitor reportable incidents in NMED.	Report to Branch management if 95% of reportable incidents are not closed in NMED within 30 days.		August 2005	RHB closed 90% of the identified open incidents in the NMED database as of May 2005. Efforts are continuing to close the remaining items. (RHB has developed new procedures to preclude repetition of this problem as noted in recommendation 7.)	May 2005
6. The review team recommends RHB submit reportable event to NMED within one month of their occurrence in accordance with the "Handbook on Nuclear Event Reporting in the Agreement States."	Establish procedures to submit reportable events to NMED within one month of occurrence.	Develop procedures and appropriate information technology enhancements. Monitor and report to RHB management if reportable events are not submitted to NMED within 30 days of occurrence.	Anderson/ Butner	September 2005	Procedures have been developed and implemented to monitor NMED reporting and ensure they are reported to RHB management if they are not submitted to NMED within 30 days.	March 2005

	Recommendation	Task	Milestones	Assigned To	Anticipated Completion Date	Status	Actual Completion Date	
7.	The review team recommends RHB establish and implement a system to track incident and allegation investigations to ensure timeliness, proper documentation, appropriate follow up, and closure.	Establish new procedures to track incident and allegation investigations to ensure proper closure.	Develop procedures and appropriate information technology enhancements. Monitor and report to RHB management if incident and allegation investigations are not properly closed within 60 days.	Anderson / Butner	November 2005	New procedures are being developed to track incident and allegation investigations. Information technology enhancements have been completed and incidents are currently being tracked. The reporting criteria to be used in the new database are under development.		
8.	The review team recommends that the Branch develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility.		See Attached for Update and Status					
9.	The review team recommends that the Branch formally establish and implement (1) a process to notify the SS&D evaluation program of all defects and incidents involving California administered SS&D sheets; and (2) a procedure for the SS&D evaluation program to investigate reports of defects and incidents for root cause and generic implications for possible subsequent reevaluation of SS&D	Develop a branch process to notify the SS&D evaluation program of all defects and incidents involving California administered SS&D sheets.	Complete Branch notification process within 10 days of defect or incident.	Perez / Fassell	August 2005	Branch notification process is in place through RHB form 5010 (Matter Requiring Investigation/Inspection) and procedures for the process is being developed.	,	
	sheets.	Develop a Branch procedure for the SS&D evaluation program to investigate reports of defects and incidents for root cause and generic implications for possible subsequent reevaluation of SS&D sheets.	Complete SS&D investigations for reports of defects and incidents within 30 days of incident. Report to RHB management any investigations exceeding 60 days.		August 2005	Investigations of reports of defects and incidents for SS&Ds are being monitored by the program. Procedures are being developed to ensure investigations are completed within 30 days or reported to upper management within 60 days.		

Recommendation	Task	Milestones	Assigned To	Anticipated Completion Date	Status	Actual Completion Date
10. The review team recommends that the State reevaluate the Nova R&D, Inc., Model CINDI neutron device with special attention to the potential exposure received by the general licensed user. If it is determined that the exposure rate exceeds that which is allowed for persons covered under the general license, the device should be reclassified for distribution to persons covered under a specific license and the SS&D evaluation certificate should be amended to reflect any required changes.	Reevaluate the Nova R&D, Inc., Model CINDI neutron device to determine if exposure rate exceeds that which is allowed for general licensing.	Conduct evaluation of radiation exposure to persons using Nova R&D, Inc., Model CINDI neutron device within 6 months and amend SS&D sheet as appropriate.	Taylor	September 2004	The Nova R&D, Inc., Model CINDI neutron device radiation exposure was assessed and determined that it should be reclassified under a specified license. This task is completed.	September 2004