STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY PETE WILSON, Governor

DEPARTMENT OF HEALTH SERVICES
714/744 P STREET
P.O. BOX 942732
SACRAMENTO, CA 94234-7320

December 24, 1997

Hugh L. Thompson, Jr.
Deputy Executive Director
for Regulatory Programs
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555-0001

Dear Mr. Thompson:

On June 18, 1997, you sent S. Kimberly Belshé, Director, California Department of Health Services, a copy of the final Integrated Materials Performance Evaluation Program (IMPEP) report on the review of the California Agreement State Program which was conducted October 21-25, 1996. In the letter of transmittal, you requested that we respond to recommendations of the IMPEP team which were included in that report.

Attached are the responses of the Radiologic Health Branch to these recommendations. For your convenience in reviewing the California responses, we have included Section 5 of the report with our responses to the recommendations immediately following the recommendation. We hope that you will find these acceptable.

I want to again express my appreciation to you and the other members of the Management Review Board and the members of the IMPEP team involved in the review of the California program. All of the California staff involved in the review and I felt that the IMPEP process was a great improvement over the former review and evaluation system. We look forward to future reviews.

If you should need additional information regarding this mater, please contact me at (916) 322-3482.

Sincerely,

Edgar D. Bailey

Edgar D. Bailey, C.H.P., Chief
Radiological Health Branch

Attachments

California Final Report

5.0 SUMMARY

As noted in Section 3 and 4 above, the review team found the State's performance with respect to each of the common and two non-common performance indicators to be satisfactory and the non-common indicator, Sealed source and Device Evaluation Program, to be satisfactory with recommendations for improvements. Accordingly, after consideration of the satisfactory finding for the non-common indicator, "Legislation and Regulations," the team recommended, and the MRB concurred, in finding the California program to be adequate to protect public health and safety and compatible with NRC's program.

Below is a summary list of recommendations and suggestions, as mentioned in earlier sections of the report, for action by the State.

1. The review team recommends that the State consider keeping a collective staff training record to help formalize technical training as an ongoing requirement for the position and to better allow management to assess the training level of the staff. Waivers granted to individual staff members from attendance at specific training courses based on past education and experience, should be documented. (Section 3.2)

Response:

The California Radiologic Health Branch (RHB) maintains a computer record and update of staff training (See Attachment 1). Because the number of health physicists employed by the program, we must prioritize their training by employing the criteria of need and seniority. The criterion of "need" is based on the area of work assigned, previous experience, education, and observations of the supervisor. Understanding our criteria for selection of staff for training is important to understanding our system of record keeping. Our record of training does not intend to duplicate other personnel records which list each individual's education and experience.

2. The review team recommends that the State take necessary action (renew the calibration contract) in order to maintain the instrument calibration schedule (Section 3.4).

Response:

RHB has entered into a contract with a private company to calibrate all radiation monitoring equipment at the required frequency. The company uses sources that are traceable to NIST and correction factors are supplied with the calibration certificate for each meter. The contract is a multi-year contract which will expire in June 2000.

3. The review team recommends that the State make a concerted effort to adopt regulations which are required for compatibility and are overdue for adoption. A special effort should be made to adopt the amendments on Notification of Incidents, the Irradiator rule, and the Definition of Land Disposal and Waste Site QA program amendment. Due to the safety benefits attendant to the QM rule, the State is encouraged to adopt a compatible QM rule. (Section 4.1)

Response:

RHB has repeatedly attempted to get legislative approval for staffing and funding for development of regulations and supporting documentation required to legally promulgate regulation in California. To date these requests have been denied. Nonetheless, RHB will continue to divert staff from other assignments and strive to ensure that required regulations are adopted in a more timely manner.

Notification of Incidents is contained in Regulation Proposal R53-94. This Regulation Proposal was filed with the Secretary of State on September 9, 1997 and is now effective.

The irradiator rule is slated for adoption. Expected effective date: September, 1998.

The Low Level Radioactive Waste (LLRW) Program will respond separately to the recommendation concerning the adoption of regulations related to low level radioactive waste.

No action is contemplated with regard to the QM rule since the NRC has provided no data or information that indicates its adoption of the QM rule has resulted in "safety benefits." Please provide this data/information.

4. The review team recommends that the State exert greater management oversight over the SS&D evaluation program. The team believes that such oversight is needed to assure full implementation of the recommendations in this area, given that some recommendations from the 1994 follow-up program review have not been fully addressed. (Section 4.2)

Response:

The SS&D evaluation program has gained a lot of attention from the California Radiation Control Program since the NRC changed its position from a mutual beneficial review to an "official compatibility" review in 1994. It was recognized in NRC's IMPEP report of the 1997 California Review that the IMPEP review team found that California had developed and implemented procedures to improve the SS&D program. The supervisor of the SS&D program self-identified some weakness in implementing these procedures and appeared committed to rebuilding the program as a model for other regulatory programs to emulate. California is committed to the achievement of

excellence. We have implemented better quality assurance for SS&D reviews by imposing mandatory peer review.

5. The review team recommends that the State consider adopting regulations compatible with 10 CFR 30.32(g) and 10 CFR 32.210. (Section 4.2)

Response:

Applications for use of SS&D must disclose information required by 10 CFR 30.32(g) as a matter of California licensing practice. The guidance provided in 10 CFR 32 Subpart D is utilized by California licensees as a basis for submission of SS&D product registration information. Submission of Subpart D information by California manufacturers is a long-standing feature of our licensing practice.

6. The review team recommends that the State determine and document in evaluation certificates whether sealed sources approved for use in well logging applications meet the requirement for insoluble as practicable. (Section 4.2)

Response:

A new checklist has been developed and put into use which outlines the requirements imposed on product design of well logging equipment, including the requirement that the active material be as insoluble as practicable. (See Attachment 2)

7. The review team recommends that the State review and possibly modify Section 1.8 of ADAC Laboratories' users manual which appears to condone direct hand contact with the sealed source. (Section 4.2)

Response:

The section was reviewed and a deficiency letter sent April 21, 1997. Responses were received on June 10, 1997 and July 15, 1997. These provided adequate technical response. The ADAC SS&D certificate was amended to reflect the change on September 17, 1997. (See Attachment 3).

8. The review team recommends that the State obtain SS&D training for those staff members that have not yet had or have limited SS&D training, either by using training offered by NRC or another Agreement State program. (Section 4.2)

Response:

The Supervisor, David Wesley, has received training at NRC workshops held September 12-15, 1995, at Gaithersburg, MD, and April 7-11, 1997, at Rockville, MD. In addition, two reviewers have received training at NRC workshops. Pete Patel

attended the workshop held September 12-15, 1995, and Tom Schell attended the workshop held April 7-11, 1997. Any future staff members will attend the same or similar training when available.

9. The review team recommends that the State develop a policy position which includes information on the useful life of a product and uses operational history data to augment prototype testing when evaluating SS&D. (Section 4.2)

Response:

The policy has been stated to the staff (see Attachment 4) and will be included in the next update (currently in progress) to Radioactive Materials Licensing Policy Memo 89-1, "Sealed Source and Device Registry Certificate Review Procedures".

10. The review team recommends that the State determine the actual use conditions for those gauging sources that do not meet the ANSI standard classification for vibration and evaluate the need to modify SS&D sheets if the condition of use is typical for industrial gamma gauging devices as indicated in ANSI N-542. (Section 4.2)

Response:

The ANSI classification for gamma gauges is divided into three categories, as follows:

Medium and High Energy - Unprotected Source	*ANSI 77C43333*
Medium and High Energy - Source in Device	*ANSI 7743232*
Low Energy	*ANSI 77C33222*

The sources in question are limited in nuclides with gamma energies below 200 KeV which are considered to be low energy and therefore, would require a classification of ANSI 77C33222. The sources were determined to have a classification of ANSI 77C65424 which meets or exceeds the requirements for low energy gamma gauge use.

11. The review team recommends that the State re-evaluate 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 special license, and the SS&D evaluation certificate should be amended to reflect any required changes. (Section 4.2)

Response:

A deficiency letter was sent to the manufacturer of the CINDI neutron device, requesting information which will help in the evaluation of the general license criteria. The licensee acknowledged receipt of the letter and requested extra time to gather all of the information necessary. If appropriate, the registration certificate will be updated with

these results. In the meantime, the licensee let their distribution license expire without submitting a renewal request; therefore, they are no longer authorized to distribute the device to general licensees. We notified the licensee of the expired license, and they have acknowledged that they will not distribute any more of the devices until they have satisfied our request for information and the license is reinstated. We have received a letter (see attachment 5) from NOVA R&D dated November 24, 1997, in response to our deficiency letter. The response will be reviewed within the next 90 days.

12. The review team recommends that the State fully implement a program of peer review of SS&D evaluations as a technical quality assurance measure. (Section 4.2)

Response:

The peer review program now includes independent technical reviews by two license reviewers. The lead reviewer will generate any deficiency letters based upon the evaluation and the registry certificate. Responses to deficiency letters will also be evaluated by both reviewers. This process will be included in the next update to Radioactive Materials Licensing Policy Memo, 89-1. "Sealed Source and Device Registry Certificate Review Procedures."

13. The review team recommends that the State amend the appropriate Industrial Nuclear Inc. SS&D certificates. (Section 4.2)

Response:

The registration certificate for the Industrial Nuclear Inc., Model IR-100 has been amended to include the corrective actions taken to meet the horizontal shock test.

14. The review team recommends that the State develop a checklist or internal procedures to follow when approving products for distribution to persons covered under a general license. (Section 4.2)

Response:

A new checklist has been developed and put into use which outlines the requirements imposed on products to be approved for distribution to persons covered under a general license (See Attachment 6). We recommend that the NRC adopt the same or similar checklists for it's staff's use.

15. The review team recommends that the LLRW program consider keeping official records of each staff member's technical training and participation in workshops, conferences, etc., in the individual's training files. (Section 4.3)

Response:

The LLRW Program will respond separately to this recommendation.

Good Practice: Along with the recommendations for California, the review team identified the following good practices in California:

1. The use of the License Review Alert Form (RH 2033) used by the inspection staff to communicate information to the licensing staff. (Section 3.3)

2. The use of the User's Declaration Form to establish a legally binding agreement between California and a licensee that can be executed by an inspector in the field to put an instant end to a serious noncompliant activity. (Section 3.4)

Response:

The two forms referenced under "Good Practice" were mailed to the attention of Cathy Schneider on August 4, 1997. These were published by the NRC as Attachments C and D in Enclosure 1 to see Agreement States letter SP-97-081 dated November 21, 1997.

Attachment 1

Name\Course	InsPro	MedUse	IP	Trans	LicPro	OGLog	RPEng	AdvLic	TelCal	HDR	2WkHPT	OR5wk	RERO	SpecTop	EnvMod	SS&D	InspPerf	Tel/Brchy	SPL-H119
Bailey, Ed														8/1/93					
Baldenweg, Paul	6/1/91	6/1/91	4/1/92	4/25/94		11/1/92						2/1/91							
Bold, Frank	11/1/86		12/1/86										4/1/60						
Brown, Lisa		9/9/96										2/5/96							
Bunn, Don	6/1/91	5/1/81	3/1/69	12/1/87		8/1/81	11/1/88	8/1/90				2/1/75	10/1/80	8/1/93					
Butner, Gary	8/1/88	2/1/85		6/1/88	11/1/84														
Chang-Taylor, Dora		8/15/94										2/7/94							
Chenoweth-Brown, Valerie	9/26/94	9/9/96	6/6/94									7/11/94							
Doerfler, Steve	4/24/95	3/1/94		6/19/95			12/6/93					2/7/94							
Edgerton, Trisha	6/1/91	3/1/93	9/1/93	12/4/95			6/5/95					7/1/90	10/1/93						
Funderburg, Bob	3/1/72	11/1/74	11/1/70	1/1/81	3/1/72	11/1/78	9/1/85		11/1/80			1/1/70	3/1/84						
Furey, Ken	8/1/88	3/1/88	5/1/85	12/1/87		11/1/91							2/1/85						
Goode, Tara		3/13/95			9/11/95					1/25/96		7/9/96							
Gottlieb, Mark	10/1/85	3/1/91	8/1/89	4/1/89									4/1/81						
Gulshan, Zubaid		8/1/93			9/11/95														
Hamrick, Barbara	7/1/91	3/16/92	6/5/95	3/23/92			12/6/93					9/10/90							
Herner, Kathleen	5/1/91	6/1/91		6/20/94								4/1/91					4/9/96		6/9/97
Hickman, John		3/1/93	9/1/93		6/1/93		12/1/92							9/1/92				6/17/96	
Honey, Don			10/1/84								3/13/95								
Hsu, Steve	9/1/86	1/1/84		5/1/87	9/1/89	11/1/83	11/1/86		3/1/84			7/1/84	9/1/91		5/15/95				
Kaufman, Kathleen	10/1/85	8/21/95	8/1/81	8/1/89								7/1/88	11/1/80						
Kent, Suzie	4/1/92	7/1/83			6/1/84							2/1/82							
Kwok, Sudana Chi		8/12/96																	
Lew, Bill	10/1/85	8/1/90		12/1/87		11/1/86	11/1/85					2/1/83	10/1/93						
Lupo, Roger			3/1/81									7/10/95							6/9/97
Montes, Mike				4/24/95								2/5/96							
Obear, Rene	2/1/85	6/1/85	6/1/91	4/1/89	12/1/88		12/1/93					8/1/86	9/1/85						
Omour, Reza	8/15/96	8/1/93		6/20/94	6/5/95					1/25/96									
Patel, Pete	6/1/85	3/1/86	3/1/85	12/1/87	9/1/86	11/1/89	12/1/93					7/1/86	11/1/85	5/1/87		9/12/95			
Pay, Stephen	9/25/95	8/15/94	6/5/95									2/6/95							
Perez, Gonzalo	9/26/94	1/1/92			5/1/92		6/5/95			1/25/96		2/1/91							
Pho, Dao	8/8/94	3/13/95		12/4/95								2/6/95							
Reyes, Bob	6/1/91	1/1/92	7/1/93	6/20/94	6/1/90														
Salgado, Cesar	9/23/96			4/29/96															
Schell, Tom		8/1/93			6/5/95											4/7/97			
Scott, Philip	9/23/96																		
Toyama, Fred	6/1/91	3/1/89	5/1/93	12/1/87	9/1/89		12/1/91						5/1/89						
Wesley, Dave		8/1/93			9/8/97						3/18/96					9/95,4/97			
Wong, Gerard	10/1/85	11/1/74		6/1/85			6/1/77		6/1/78					9/1/91					
Wong, Jeff	6/1/91	8/21/95		8/1/91			12/1/91							6/1/94					

CHECKLIST FOR ADDITIONAL REQUIREMENTS IN THE EVALUATION OF SEALED SOURCES FOR WELL LOGGING

MANUFACTURER/DISTRIBUTOR: _____

MODEL #: _____ _____ REGISTRATION #: _____

REVIEWER: _____ DATE: _____

Description	OK/Def	Comments
Labeling		
Does the smallest component of the source, source housing, or logging tool (which contains radioactive material inside) that is transported as a separate piece of equipment, bear a durable, legible, and clearly visible marking or label containing the following?: ____ The radiation symbol (no color requirements) ____ The wording "DANGER (or CAUTION) RADIOACTIVE MATERIAL"		
Leak Testing		
Is the maximum leak test interval set at 6 months?		
Design		
Is the source doubly encapsulated when containing non-gaseous radioactive material? (A doubly encapsulated source may not, in fact , be doubly encapsulated if, in the process of constructing the secondary encapsulation it is subjected to stresses that destroy its integrity. Review the submitted drawings and description of fabrication. A written description of the source fabrication process should always accompany drawings of the source since a fabrication process may not be correctly inferred from drawings alone.)		
Is the radioactive material in a form which is as nondispersible as practical and as insoluble as practical when containing non-gaseous radioactive material?		
Prototype Testing		
Temperature: For sources containing non-gaseous radioactive material, was the test source held at -40°C for 20 minutes, 600°C for 1 hour, and then subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds?		
Impact: For sources containing non-gaseous radioactive material, was a 5 kg steel hammer, 2.5 cm in diameter, dropped from a height of 1 m onto the test source?		
Vibration: For sources containing non-gaseous radioactive material, was the test source subjected to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes?		
Puncture: For sources containing non-gaseous radioactive material, was a 1 gram hammer and pin, 0.3 cm pin diameter, dropped from a height of 1 m onto the test source?		
Pressure: For sources containing non-gaseous radioactive material, was the test source subjected to an external pressure of 24,600 pounds per square inch absolute (1.695×10^7 pascals)?		