

**DATED: JANUARY 4, 2000**

**SIGNED BY: CARL J. PAPERIELLO**

James W. Stratton, M.D., M.P.H.  
Deputy Director  
California Department of Health Services  
Prevention Services  
714 P Street, Room 1492  
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Dear Dr. Stratton:

On December 20, 1999, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the California Agreement State Program. The MRB found the California program adequate to assure public health and safety and compatible with NRC's program.

Section 5.0, page 22, of the enclosed final report presents the IMPEP team's recommendations. We request your evaluation and response to recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review will be in approximately 4 years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

Carl J. Paperiello  
Deputy Executive Director  
for Materials, Research  
and State Programs

Enclosure:  
As stated

cc: Edgar D. Bailey, C.H.P., Chief  
Radiological Health Branch  
California Department of Health Services

Larry Barrett, D.V.M., M.S., Chief  
California Department of Health Services

T. Pearce O'Kelley, OAS Liaison to MRB

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bcc: Chairman Meserve  
Commissioner Dicus  
Commission Diaz  
Commissioner McGaffigan  
Commissioner Merrifield

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF CALIFORNIA AGREEMENT STATE PROGRAM

October 4 - 8, 1999

# FINAL REPORT

U.S. Nuclear Regulatory Commission

## 1.0 INTRODUCTION

This report presents the results of the review of the California radiation control program. The review was conducted during the period October 4-8, 1999, by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Georgia. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 25, 1998, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period October 26, 1996 to October 3, 1999 were discussed with California management on October 7, 1999.

A draft of this report was issued to California for factual comment on November 4, 1999. The State responded in a letter dated December 6, 1999 and an electronic mail message dated November 18, 1999. The Management Review Board (MRB) met on December 20, 1999, to consider the proposed final report. The MRB found the California radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The California Agreement State program is located in the Department of Health Services (the Department). Within the Department, the Radiological Health Branch (the Branch) located in the Division of Food, Drug, and Radiation Safety (the Division) administers the radioactive materials program. Organization charts for the Department, the Division and the Branch are included as Appendix B. The California program regulates approximately 2076 specific licenses authorizing agreement materials. The review focused on the program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of California.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the State on August 13, 1999. The Branch provided responses to the questionnaire on September 22, 1999. A copy of the questionnaire responses is included as Appendix G to proposed final report.

The review team's general approach for conduct of this review consisted of: (1) examination of California's responses to the questionnaire; (2) review of applicable California statutes and regulations; (3) analysis of quantitative information from the Branch's licensing and inspection data base; (4) technical evaluation of selected licensing and inspection actions; (5) field accompaniments of seven California inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the radiation control program's performance.

Section 2 below discusses the Department's actions in response to recommendations made following the previous program review. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings,

recommendations, and a good practice identified during the review. Recommendations made by the review team are comments that relate directly to program performance by the Department. A response is requested from the Department to all recommendations in the final report.

## 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous program review, which concluded on October 25, 1996, fifteen recommendations were made and the results transmitted to S. Kimberly Belshe, Director, Department of Health Services, on June 18, 1997. The review team's evaluation of the current status of the recommendations is as follows:

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)

Current Status: The Branch maintains a collective electronic record of staff training which is continuously updated. Training assignments are made by supervisors and are based on work assignments and the individual's past training and experience. Although formal waivers from specific classes have not been granted to individual staff members, personnel records contain information pertaining to the individuals' qualifications, including education and experience. The Branch is currently developing a written training program similar to "NRC/OAS Working Group Recommendations for Agreement State Training Programs." (See Section 3.3 for more details) This recommendation is closed.

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

Current Status: A multi-year contract with a private company to calibrate all radiation monitoring equipment was signed. The existing contract will expire in June 2000. This recommendation is closed.

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 Quality Assurance program amendment. Due to the safety benefits attendant to the Quality Management rule, the State is encouraged to adopt a compatible Quality Management rule. (Section 4.1)

Current Status: The Notification of Incidents rule was adopted in September 1997. Due to the complex and lengthy process to adopt regulations, the Branch has decided not to adopt the Irradiator rule (58 FR 7715) but have incorporated legal binding license conditions in affected licenses. The Definition of Land Disposal and Waste Site Quality

Assurance program amendment as adopted in July 1999. The NRC supported the Branch conserving rulemaking resources by addressing the new Part 35 when it is finalized and thus not adopting the current Quality Management rule (see the May 1, 1998 NRC letter to E. Bailey).

Since the last review, the Branch has spent considerable effort to adopt compatibility regulations in a more timely manner. The Certification, Registration and Standards (CRS) Section currently expends 1.6 FTE on regulatory development. In addition, the Branch has two full time attorneys on staff who provide support in this area. Finally, a budget proposal to establish a regulation unit in the Branch has been submitted to the California legislature for next fiscal year. This recommendation is closed.

4. The review team recommends that the State exert greater management oversight over the Sealed Source and Device (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)

Current Status: The current status of the SS&D program is discussed in Section 4.2 of this report. The SS&D Unit still operates under the management procedure, Radioactive Materials Licensing Policy Memo 89-1 dated March 1, 1995, that was found inadequate in the previous review. Quality of the SS&D evaluation is provided by the personal experience of the SS&D Unit leader and one staff member who have had training and case work experience. The team has identified specific recommendations in Section 4.2 of this report regarding the need to formalize management oversight of the SS&D Unit. Therefore, this recommendation is closed.

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)

Current Status: Due to the complex and lengthy process to adopt regulations, the Branch has decided not to adopt these regulations, but has incorporated them by legally binding requirements. On September 2, 1997, the SS&D Unit leader sent an e-mail instruction to the staff that NRC's policy should be followed to determine what source and device designs require an evaluation. The instruction references NRC Policy and Guidance Directive 84-22, Revision 1, dated June 27, 1995, as the document to be used. The action would be considered adequate if implemented by staff; however the team noted that one person, who had been working on SS&D cases during the review period but had left by the time of this review, did not receive the e-mail. Similarly, a new staff member, who was hired after the issuance of the e-mail, has not received it. The failure to formalize this change in policy is addressed as part of a recommendation in Section 4.2.1 of this report. Therefore, this recommendation is closed.

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)

Current Status: The Branch developed a checklist entitled "Checklist for Additional Requirements in the Evaluation of Sealed Sources for Well Logging," dated April 24, 1997. The checklist adequately addresses the issue of insolubility. This recommendation is closed.

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

Current Status: The Branch initiated the amendment process and is still working on the case. Specifically, the Branch sent a deficiency letter to the licensee in the process of amending the certificate. The licensee's initial response was insufficient, the Branch has followed up with telephone calls and other notifications, which are documented in the file, but has not received a sufficient response yet. The case is being handled properly with the normal process of State/licensee interaction for SS&D cases. The Branch's staff has developed an adequate technical position regarding the issue identified in the previous IMPEP review. This recommendation is closed.

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)

Current Status: Currently four members of the Branch's staff are assigned to conduct SS&D evaluations. Two staff members have completed the NRC workshop during the review period. The other two members were hired after the workshop was last offered. They are scheduled to attend the next available workshop. This recommendation is closed.

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

Current Status: The issue of useful life is still subject of discussion in the SS&D community. Specifically, the NRC and the Agreement States discussed the issue in several meetings regarding a definition of the term as well the desirability of including useful life in the certificates. Presently, there are no final conclusions on useful life on a nationwide basis. It is a subject of further studies. Consequently, the State has not adopted a permanent position pending further developments. The issue of operational history data for prototype testing has been implemented. The team reviewed a number of cases and found that, where applicable, the operational data have been properly utilized and documented. This recommendation is closed.

10. The review team recommends that the State determine the actual use conditions for those gauging sources that do not meet the American National Standard Institute (ANSI) 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)



Current Status: The Branch staff conducted a reevaluation of the certificate which lead to this recommendation, and found it to be correct. The review team also reviewed the case and determined that the statements in the certificate were in accordance with the ANSI standard and that the previous recommendation resulted from a misunderstanding. This recommendation is closed.

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 specific license and the SS&D evaluation certificate should be amended to reflect any required changes. (Section 4.2)

Current Status: The Branch sent a deficiency letter to the licensee in the process of re-evaluating the device. The licensee's initial response was incomplete, and the Branch has followed up with further requests. During the reevaluation process, the manufacturer failed to pay the appropriate license fee and the Branch has yet to receive payment. The Branch's staff is considering declaring the case abandoned. The case was handled properly with the normal process of State/licensee interaction for SS&D cases. This recommendation is closed.

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

Current Status: The team found during this review that all certificates reviewed were signed by two reviewers. All staff members are aware of the requirement. However, the Branch has not yet developed a new procedure to formalize this process. Specifically, the Branch still uses the Radioactive Materials Licensing Policy Memo, 89-1, "Sealed Source and Device Certificate Review Procedures," dated March 1, 1995, which precedes the previous review and had been found inadequate at that time. Section 3.1.3 of the Memo states that the draft certificate is to be "routed to one or two other reviewers" and that "[n]ormally one peer review is needed for sealed sources and two peer reviews are needed for devices." This issue is discussed in Section 4.2.1 and 4.2.2 of this report and is addressed as a new recommendation. This recommendation is closed.

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

Current Status: The Branch amended the certificate (CA-0384-D-109-S) and issued it on February 24, 1997. The team reviewed the amendment and found it adequate. This recommendation is closed.

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)

Current Status: The Branch developed and issued a checklist entitled "Checklist for Additional Requirements in the Evaluation of Devices Used Under General Licence," dated April 24, 1997. The team reviewed the checklist and found it adequate. This recommendation is closed.

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)

Current Status: Prior to the termination of the Low Level Radioactive Waste (LLW) program in July 1999, training records were maintained as of January 1997. This recommendation is closed.

### 3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators are: (1) Status of Materials Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

#### 3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing the status of the materials inspection program: inspection frequency, overdue inspections, initial inspection of new licensees, and the timely dispatch of inspection findings to licensees. The review team's evaluation is based on the California questionnaire responses relative to this indicator, data gathered independently from reports from the Branch's inspection data tracking system, the examination of completed licensing and inspection casework, and interviews with the managers and staff.

The review team's evaluation of the Branch's inspection priorities revealed that inspection frequencies for each type of license were the same or more frequent than similar license types listed in the NRC Inspection Manual Chapter (IMC) 2800, with one exception. In July 1999, the State changed the inspection frequency of high-dose rate afterloader (HDR) units from one year to three years. The NRC inspects HDR units on an annual basis. The State made the change following a review of all inspection reports of HDR licenses since 1989, and finding that there "has been no significant violations" with the operations of the HDR units. The review team noted that the State established written procedures to extend or reduce the next inspection interval based upon licensee performance. The review team found this acceptable. During the MRB, the process for evaluating, analyzing, and supporting a change in the inspection frequency for a class of licensees based on performance was deemed a good practice.

The Inspection, Compliance, and Enforcement (ICE) Section staff uses a computer database program to track inspection due dates. The printout identifies the last inspection date, the inspection due date and the 25% overdue date (consistent with IMC 2800). The staff has access to the database information by updates and reports issued by the ICE Section. The ICE Section at the Sacramento office generates, on a quarterly basis, the schedule for the inspection groups in the field offices. Inspectors in the six field offices and the Sacramento office perform inspections

according to the quarterly scheduling report generated by the Sacramento office. A procedure exists for establishing the date for the next scheduled inspection based on the date of the last inspection and the inspection priority. Since the inspection frequencies for routine inspections are more frequent or as frequent as those required by the NRC (with the exception of HDR units), the scheduling of inspections does not fall outside of IMC 2800.

In their response to the questionnaire, the Branch indicated that they had no inspections overdue by more than 25% of the NRC frequency. During the review of 20 inspection reports, the team noted that there was only one inspection that was overdue by this criterion. In this case, management decided to delay this inspection since the license was undergoing a significant license revision.

With respect to initial inspections of new licensees, the team evaluated those new licenses issued since the last review against the inspection files to determine their initial inspection date. The Branch's policy is to perform initial inspections within six months of receipt of licensed material. About every six months, the ICE Section telephones new licensees to determine the status of their activities. The licensee's status, (e.g., no receipt of licensed material) is entered into the inspection schedule database. The Branch has a number of licensees in this category extending several years after license issuance. This policy differs from IMC 2800 which requires that initial inspections be performed within six months of receipt of licensed material, within six months of beginning licensed activities, or within one year of license issuance, whichever comes first. The review team confirmed that initial inspections are performed in accordance with the State's policy and found this acceptable.

The review team also evaluated the status of reciprocity inspections. During the current review period, approximately 160 requests for reciprocity were filed with the program. The ICE Section noted that they have not met their reciprocity inspection goals during this review period. The Branch's reciprocity inspection goals are similar to NRC's IMC 1220 criteria. Recently, the ICE Section implemented an improved tracking system to ensure better compliance with reciprocity inspections goals, and have been successful in increasing the number of reciprocity inspections. In 1999, 34 licensees applied for reciprocity. So for this year, the Branch has inspected 15 and needs to complete 3 more by the end of the year to complete their goal.

Timeliness of inspection correspondence issuance was evaluated during the inspection casework review. Of 20 inspection letters reviewed by the team, all were issued to the licensee within 30 days and usually within the first week. Some of the program's routine inspections result in the issuance of a State Form 2514 field compliance form which is similar to NRC's Form 591. Other inspection findings are dispatched to licensees within 30 days of completing an inspection. The review team considered the issuing of inspection correspondence outstanding, especially considering that the Branch conducts approximately 600 inspections annually.

The ICE Section coordinates inspection correspondence from the six field offices and the Sacramento office. The coordination serves to ensure consistency for compliance of licensed activities across the State. In addition, the ICE Section has an independent QA Unit that provides oversight of the inspection program. The QA Unit develops policy, communicates information, and audits the inspection functions for consistency with program requirements among the seven

inspection units. The QA Unit has one staff member with considerable experience in the QA of materials functions. Since the inception of the QA Unit, the team noted several program improvements. The team recognizes this as a good practice in Section 3.5.

Based on the IMPEP evaluation criteria, the review team recommends that California's performance with respect to the indicator, Status of Materials Inspections, be found satisfactory.

### 3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 20 radioactive material inspections conducted during the review period. The casework included at least one inspector from each of the six field offices and the Sacramento office and covered inspections of various types including: medical institutions, industrial radiography, nuclear pharmacy, irradiator, academic broad scope, medical broad scope, waste processing, HDR and reciprocity. Appendix C lists the inspection casework reviewed for completeness and adequacy with case-specific comments.

Inspection reports are reviewed and signed by supervisors. In addition, the reports are reviewed by the QA health physicist to ensure consistency between the various offices. The QA unit developed boilerplate language for compliance letters and violations to ensure consistency. Also, the QA health physicist audits the reports for the ICE Section. Licensees' responses are evaluated and replied in a timely manner. The inspection files were found to be complete and in good order.

California's inspection procedures are consistent with NRC procedures. The ICE Section attempts to conduct inspections unannounced, but sometimes inspections are announced a few days before the inspection. The review team noted that eight of the routine inspection files evaluated were unannounced.

Based on casework, the review team noted that the routine inspections covered all aspects of the licensees' radiation programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were performed when appropriate and for training purposes.

Field notes have been developed to cover most types of inspections that are conducted by the Section. The QA Unit recently amended the field notes to include the scope of the licensee's program. These field notes provide documentation for the scope of the licensees' program and cover all areas that need to be reviewed. The information contained in the field notes is comparable with NRC's Inspection Procedure 87100.

Inspection accompaniments are performed by the Sections's QA health physicist and senior inspectors. In the Section, senior inspectors perform supervisory functions. The Section's goal is to have both the QA health physicist and the inspector's supervisor accompany each inspector annually. The review team noted that inspectors are accompanied at least once a year.

Seven State and County inspectors were accompanied during the weeks of September 13, September 20 and September 27, 1999. Review team members performed the accompaniments with new inspectors from all field offices (except San Jose) and the Sacramento office. The accompanied inspections included: a pool irradiator facility, medical facilities, industrial radiography, and research and development facilities. These accompaniments are also identified in Appendix C.

During the accompaniments, the Branch inspectors demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were well prepared and thorough in their audits of the licensees' radiation safety programs. Overall, the technical performance of the inspectors was good, and their inspections were adequate to assess radiological health and safety at the licensed facilities.

On September 22, 1999, a review team member performed an on-site review of the State's Sanitation and Radiation Laboratories Branch located in Berkeley, California. The laboratory is responsible for analyzing environmental samples and contamination surveys collected by inspectors during the course of their inspections at licensee facilities. The team observed the staff demonstrate how samples are received, logged in and counted, and how reports are generated and filed. Also, during a tour of the facility, the laboratory staff demonstrated quality control aspects for radiochemistry analyses including instrument quality control and QA checks on analytical data. The team noted that appropriate procedures were in place to receive, analyze and report results of radiological data collected during inspections at licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommends that California's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

### 3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials program staffing level and staff turnover, as well as the technical qualifications and training of the staff. To evaluate these issues, the review team examined the Branch's questionnaire responses relative to this indicator and interviewed the program management and staff.

The Branch is staffed with The Branch Chief, Assistant Chief, four Section Chiefs, staff counsel, health physics staff, and administrative support staff. With regard to the Agreement State program, the Radioactive Materials Licensing (Licensing) Section has 22 health physicists, the ICE Section has 19 health physicists, and the CRS Section has three health physicists. In response to the questionnaire, the Branch reported that the Branch Chief and the Assistant Chief each spend about 50 percent of their effort supervising the radioactive materials program, the Licensing Section manager devotes one FTE to the materials program, and the CRS Section manager and ICE Section managers devote a portion of their time to the materials program. Including administrative support staff, the total Branch effort for radioactive materials is approximately 70.5 FTE

The Branch has four field offices (Berkeley, Los Angeles, Brea, and San Jose) in addition to the main office in Sacramento where inspectors are dispatched. The Branch has contracts with Los Angeles County and San Diego County to perform material inspections. The field offices

and the counties report to the ICE Section Chief. Approximately 3.5 FTE is expended by the counties for materials inspection and oversight. This is included in the 70.5 FTE expended by the Branch.

The Branch's response to the questionnaire indicated that eight staff members left the program and 15 staff members were hired during the review period. The Branch currently has filled all vacancies permitted. However, the Branch has several technical and administrative positions that cannot be filled due to budget restraints and lack of legislative approval. Nevertheless, the Branch continues to seek new authorizations for new positions from the California legislature to sufficiently staff all aspects of the Branch's radiation protection program. The team believes that full staffing of the program is needed to complete Bureau's business reprocess re-engineering initiative and reduce the backlog in licensing and SS&D registrations. Further discussion on this matter is found in Sections 3.4 and 4.2.2.

The qualifications of the staff were determined from the questionnaire, training records, and interviews of personnel. The team found the staff well qualified from an education and experience standpoint. All have Bachelor's degrees in the sciences, or equivalent training and experience. Training assignments are made by supervisors and managers and are based on work assignments and the individual's past training and experience. License reviewers and inspectors have attended most of the training courses prescribed in the "NRC/OAS Working Group Recommendations for Agreement State Training Programs" commensurate with their assignment and are familiar with California regulations, policies, and procedures. The Branch has a working draft training plan for the Branch staff and plans to complete it by the end of the year. During discussions with Branch management, the team determined that the training plan for material staff will be comparable with the IMC 1246 and "NRC/OAS Working Group Recommendations for Agreement State Training Programs."

The team noted that no members of the Branch have completed the NRC-sponsored Irradiator Technology course (H-315) or equivalent training. The team's evaluation of inspection and licensing actions involving irradiator programs did not identify deficiencies related to lack of training in these areas. The Branch's license reviewers and inspectors produced quality inspection and licensing products. Although the irradiator course is a supplementary or specialized course, the team believes that training in this area is beneficial and that staff performing licensing actions or inspection activities on pool irradiators should have the irradiator course or equivalent training.

The Branch has also a number of in-house training initiatives that supplement formal training courses. During the last year, three inspectors with little or no experience in materials inspections were sent to a two-week internship program at State universities to gain experience and insight in the operations of academic broad scope licensees. The Branch also conducts semiannual meetings for inspectors and licensing staff. These meetings typically include topics on policy changes, event reporting, instrument demonstrations, QA and topic training, often by outside speakers. The Branch has also used the Gollnick home study course on basic radiation protection technology to prepare staff for the five-week health physics training course.

The Branch management are supportive of staff training and demonstrated a commitment to staff training during the review. The Branch has budgeted sufficient training funds, but staff attendance at training courses outside California is limited during the first four to five months in the State's fiscal year (starts on July 1) due to State restrictions on out-of-state travel without approval by the Governor's office.

The review team discussed the role of the Nuclear Medicine Council with the Branch Chief. The council serves as an advisory committee to the Branch for seeking advice on nuclear medicine issues involving radioactive material and improve communication within the regulated community. Members of the council have provided the Branch with high quality topic information on new technologies in the nuclear medicine field. Meetings are held quarterly. The team evaluated meeting minutes from 1998 and 1999. No evidence of any conflict of interest issues was identified.

Based on the IMPEP evaluation criteria, the review team recommends that California's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

#### 3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the staff for 17 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were evaluated for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. The casework was evaluated for timeliness, adherence to good health physics practices, reference to appropriate regulations, documentation of safety evaluation reports, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, peer or supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions that had been completed in the review period. The licensing casework included work by thirteen staff reviewers from the Branch's Medical, Industrial & General Licensed Devices, and SS&D/Financial Surety licensing units. The cross-section sampling included the following types: academic medical broad scope; teletherapy; industrial radiography; medical institution; brachytherapy; HDR; nuclear pharmacy; in vitro laboratory; research and development; large pool irradiator; small irradiator; medical private practice; mobile HDR transportable service; veterinary medicine; well logging; mobile nuclear medicine; and portable gauge. Types of licensing actions selected for evaluation included three new licenses, nine amendments to existing licenses, four license renewals, and one termination. A list of licenses evaluated for license reviews may be found in Appendix D.

The team found that the licensing actions were very thorough, complete, consistent, of high quality and properly addressed health and safety issues. The licensee's compliance history is taken into account when reviewing renewal applications as determined from documentation in the

license files and discussions with the license reviewers. The casework evaluation indicated that the staff follows their licensing guides during the review process to ensure that licensees submit the information necessary to support their request. The review team noted that any licenses authorizing the use of HDRs, nuclear medicine mobile, nuclear pharmacy, large pool irradiator, and industrial radiography contained standard conditions as appropriate for each license type. Licensing actions involving decommissioning activities are handled by the SS&D staff.

During the review, the team determined that approximately 600 licensing actions were pending. Based on the licensing statistics provide, 261 of these actions (mostly renewals) have been pending for at least one year or more. Management and the materials licensing staff have explained that this backlog is due to a shortage of staff and the receipt of a large number of financial surety applications. Management is currently addressing the backlog by requesting additional staff from the State legislature and reassignment of other personnel. Although the team did not identify any immediate health and safety concerns created by the backlog, the team expressed their concern regarding the backlog during the exit meeting with Department Management.

The team found that terminated licensing actions are well documented, including the appropriate material transfer records and survey records. The files demonstrate that documentation of proper disposal and/or transfer was provided.

Licenses are renewed on a seven-year frequency. Licenses that are under timely renewals are sent a timely filed letter to keep the license current while the license is undergoing the renewal process. Licenses that are not under timely renewals are not given authorization to continue use and possession of radioactive materials until their license has been renewed. Deficiencies are addressed by additional information letters and documented telephone logs which used appropriate regulatory language. Prior to the issuance of a license document, each licensing action receives a peer review and is signed off by the Senior Health Physicist supervisor of the applicable licensing unit.

Based on the IMPEP evaluation criteria, the review team recommends that California performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

### 3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the Branch's actions in responding to incidents, the review team examined the Branch's response to the questionnaire regarding this indicator, evaluated selected incidents reported for California in the "Nuclear Material Events Database" (NMED) against those contained in the California files, and evaluated the casework and supporting documentation for 13 material incidents. The team also reviewed the ICE Section's response to 12 allegations, including five allegations referred to the State by NRC, during the review period. A list of incident files examined along with case specific comments is contained in Appendix E.

The review team interviewed program management and staff to discuss the Branch's incident and allegation process, file documentation, the State's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC. The 13 incidents selected for review included the



following types: transportation, loss of control, misadministration, damaged equipment, release of material, lost/stolen material, and leaking source.

When an incident or allegation is received, a Form 5010, "Matter Requiring Investigation/Inspection," is filled out by the staff member who first receives the information. The responsibility for initial response to incidents and allegations involving radioactive material, both falling under the category of "investigations," is then assigned to a technical staff member by a manager. Though Branch procedures state that the investigation should be completed within 30 days for normal incidents, most cases are handled within a few days of notification. Once the investigation has been closed out by management, a "Materials Investigation Closing Memo" is completed and placed in the file for the investigation. The investigation is then reviewed by the QA Health Physicist. A copy of the Form 5010 is placed in the licensing and inspection files as well. The ICE Section has written procedures for handling investigations.

The review team found that the ICE Section's responses to incidents and allegations were complete and comprehensive. Initial responses were prompt and well-coordinated. The level of effort was commensurate with the health and safety significance. Inspectors were dispatched for on-site investigations when appropriate and the ICE Section took suitable enforcement action. The review team found the documentation of incidents to be consistent and that incidents were followed up at the next inspection.

The team reviewed an investigation involving a damaged source changer that was initially closed out before a number of safety issues were resolved. The QA Health Physicist review of this investigation identified these issues and the investigation was reopened. The issues were then properly addressed. The team also noted other examples where the QA Health Physicist identified issues requiring additional follow-up during the audit of the incident reports. In Sections 3.1 and 3.2 of the report, the team noted examples where the QA Unit has had positive impacts on the inspection program since its inception three years ago. The review team recommends that the use of a QA Health Physicist be found a good practice, specifically for larger radiation control programs. The position strengthens the Division's performance and ensures that health and safety issues are properly addressed.

Management and staff are familiar with the guidance contained in the "Handbook on Nuclear Event Reporting in the Agreement States" (Handbook). The review team queried the incident information reported to the NMED system for California for the review period which identified 96 incidents. During discussions with the ICE Section Chief, it was discovered that, although incidents that required immediate notification were promptly reported, a number of incidents were not yet submitted to NMED but were to be reported during California's next report. Overall, only two incidents that should have been reported had not been reported by the ICE Section, as well as one gauge that was not reported when it was recovered.

The ICE Section chooses to send information by hard copy to NRC on a quarterly basis for inclusion in the incident database. The ICE Section stated that they initially encountered difficulties with the NMED software which impacted their ability to report incidents. The Handbook indicates that the State should report an event to NMED within one month of its occurrence. The team recommends that the Branch submit reportable events to NMED within one month of their

occurrence in accordance with the “Handbook on Nuclear Event Reporting in the Agreement States.”

During the review period, 16 allegations were referred to the Branch by the NRC. The casework for five of these allegations was reviewed as well as the casework for eight additional allegations reported directly to the Branch. The review of the ICE Section’s allegation files indicated that the ICE Section took prompt and appropriate action in response to the concerns raised. The review team noted that all documentation related to the investigation of allegations was maintained in the investigation file. Through discussions with ICE staff members and review of casework, the review team was able to establish that allegeders were properly notified of investigation results.

Based on the IMPEP evaluation criteria, the review team recommends that California’s performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory.

#### 4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in evaluating Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) SS&D Evaluation Program; (3) LLW Disposal Program; and (4) Uranium Recovery Program. California’s Agreement, does not include uranium recovery facilities, so only the first three non-common performance indicators were applicable to this review.

##### 4.1 Legislation and Program Elements Required for Compatibility

###### 4.1.1 Legislation

California became an Agreement State in 1962. The currently effective statutory authority is derived from the Radiation Control Law contained in Division 20, Section 7.6 of the California Health and Safety Code. Title 17 of the State’s Code of Regulations contains specific radiation control requirements including those addressing the disposal of LLW. The Branch is designated as the State’s radiation control agency and implements the radiation control program.

###### 4.1.2 Program Elements Required for Compatibility

The California Code of Regulations, Title 17 (Public Health), Division 1 (the Department), Chapter 5 (Sanitation), Subchapter 4, applies to all ionizing radiation. California requires a license for possession and use of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides. California also requires registration of all equipment designed to produce x-rays and other ionizing radiation.

Since the last review, the Branch has expended additional resources on regulatory development. This area was one of the first activities evaluated by the Branch as part of their business process re-engineering initiative. An examination of the State’s complex and lengthy administrative rule making process identified at least 31 steps and found that the process takes at a minimum of one year (and often longer) from the development stage to the final filing with the Secretary of State, after which the rules become effective in 30 days. The regulation adoption process is provided in

the California Government Code, Article 6, Sections 11349 through 11349.6. The public, the NRC, other agencies, and all potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated as appropriate before the regulations are finalized, approved, and filed with the Secretary of State. The State can adopt other agency regulations by reference which has been done with respect to transportation regulations adopted by the U.S. Department of Transportation (DOT) and 10 CFR Part 20 radiation protection regulations adopted by the NRC.

As part of the regulatory development process, the Branch has initiated in the last year the reading out loud of draft regulations during a meeting to the Branch's supervisory, technical and administrative staffs. The purpose of the draft regulation readings is to identify conflicts with other portions of the regulations, gaps, viability of processing times imposed on licensees or the State, and the general readability of the proposed regulation. The team recommends the regulation readings as a good practice since it provides the technical and administrative staffs, the individuals responsible for implementing the regulations and those most often in contact with the licensees, the opportunity to identify potential problems before the regulations are finalized.

California law requires that guides, criteria, manuals, instruction standards of general application or other rule be enforced only as an adopted regulation. The review team noted that the Branch in their response to the questionnaire stated that they are using license conditions to meet the compatibility requirements for commercial irradiators, industrial radiography and some medical licensees. The team discussed this issue with the Branch's legal counsel and determined that the radiation regulations contain language that allows the Branch to issue a license with legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The team evaluated the State's response to the questionnaire, reviewed the status of regulations required to be adopted by the State during the review period, and verified the adoption of regulations with data obtained from the Office of State Programs Regulation Assessment Tracking System. The review team noted that since the October 1996 review, the State updated the California regulations to be compatible with NRC regulations as follows:

- ! "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757 and 56 FR 64980) that became effective on October 15, 1991 was adopted by the State on September 9, 1997;
- ! "Licensing and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 amendment (58 FR 7715) that became effective on July 1, 1993 and is enforced through legally binding requirements during licensing;
- ! "Definition of Land Disposal and Waste Site QA Program," 10 CFR Part 61 Amendments (58 FR 33886) that became effective on July 22, 1993 was adopted by the State on July 19, 1999;
- ! "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767 and 65243) that became effective on January 1, 1995 and adopted by the State on October 12, 1999;

- ! "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendment (60 FR 28323) that became effective on June 30, 1995 and is enforced through legally binding requirements during licensing;
- ! "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective on November 24, 1995 and adopted by the State on October 9, 1997.

The team reviewed licenses issued by the Branch for Part 36 irradiators and industrial radiography and determined that the legally binding requirements were in use regarding the two above-mentioned NRC amendments.

The Branch has not taken action on the following two NRC amendments for the reasons indicated. Upon resolution of the outstanding issues, the Branch indicated that they will be addressed in upcoming rulemakings or by adopting alternate legally binding requirements.

- ! "Quality Management Program and Misadministrations," Part 35 amendments (56 FR 34104) that became effective on January 27, 1992. The NRC supported the Branch conserving rulemaking resources by addressing the new Part 35 when it is finalized and thus not adopting the current Quality Management rule (see the May 1, 1998 NRC letter to E. Bailey).
- ! "10 CFR Part 71: Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendments (60 FR 50248) that became effective on April 1, 1996. The State will await NRC's resolution of the issue if an Agreement State should be forced to incur the expense of promulgating mirroring regulations for activities when DOT has parallel, superseding regulations.

The team identified the following regulation changes and adoptions that will be needed in the future, and the State related that the regulations would be addressed in upcoming rulemakings or by adopting alternate legally binding requirements:

- ! "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994;
- ! "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendment (60 FR 7900) that became effective on March 13, 1995 and adopted by the State on September 10, 1998;
- ! "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 25983) that became effective March 1, 1998. The Agreement States were to promulgate their regulations no later than March 1, 1998, so that NRC and the State would require this national system to be effective at the same time. The State adopted Part 61 compatible regulations for this amendment on July 9, 1999. Part 20 compatible regulations for this amendment are currently pending;

- ! "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective on August 14, 1995;
- ! "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective on October 20, 1995 and adopted by the State on September 10, 1998. The State is enforcing the Part 35 regulations through legally binding requirements during licensing. Part 20 compatible regulations for this amendment are currently pending;
- ! "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective on June 17, 1996 and adopted by the State on September 10, 1998. Part 20 compatible regulations for this amendment are currently pending. The team determined that the State has compatible regulations in place for amended Parts of 10 CFR Parts 30, 40, 61, and 70;
- ! "Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act," 10 CFR Part 20 amendment (61 FR 65120) that became effective January 9, 1997;
- ! "Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State," 10 CFR Part 150 amendment (62 FR 1662) that became effective February 27, 1997;
- ! "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Parts 20 and 35 amendments (62 FR 4120) that became effective May 29, 1997. The State is enforcing the Part 35 regulations through legally binding requirements during licensing. Part 20 compatible regulations for this amendment are currently pending;
- ! "Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations," 10 CFR Parts 30, 34, 71, and 150 amendments (62 FR 28947) that became effective June 27, 1997.
- ! "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997. Part 20 compatible regulations for this amendment are currently pending. The team determined that the State has compatible regulations in place for amended Parts of 10 CFR Parts 30, 40, and 70.
- ! "Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea," 10 CFR Part 30 amendment (62 FR 63634) that became effective January 2, 1998.
- ! "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 13773) that became effective February 12, 1998.

- ! “Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations,” 10 CFR Part 34 amendment (63 FR 37059) that became effective July 9, 1998.
- ! “Minor Corrections, Clarifying Changes, and a Minor Policy Change,” 10 CFR Parts 20, 32 and 39 amendments (63 FR 39477 and 63 FR 45393) that became effective October 26, 1998.
- ! “Transfer for Disposal and Manifests; Minor Technical Conforming Amendment,” 10 CFR Part 20 (63 FR 50127) that became effective November 20, 1998.

A number of amendments that include changes to 10 CFR Part 20 will be adopted with the completion of regulation package R-31-98. This particular package will change the effective date in the California regulations for adoption of 10 CFR Part 20 by reference. This package is currently under review in The Department’s Office of Regulations. The team noted that the CRS Section has initiated work to adopt all NRC amendments.

It is noted that Management Directive 5.9, Handbook, Part V, (1)(C)(III) provides that the above regulations issued prior to September 3, 1997 should be adopted by the State as expeditiously as possible, but not later than three years after the September 3, 1997 effective date of the Commission Policy Statement on Adequacy and Compatibility, i.e., September 3, 2000.

Based on the IMPEP evaluation criteria, the review team recommends that California’s performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory.

#### 4.2 Sealed Source and Device (SS&D) Evaluation Program

In assessing the Branch’s SS&D evaluation program, the review team examined information provided by the Branch in response to the IMPEP questionnaire on this indicator. A review of selected new and amended SS&D evaluations and supporting documents covering the review period was conducted. The team observed the SS&D Unit’s use of guidance documents and procedures, and interviewed the staff, and the SS&D Unit leader involved in SS&D evaluations.

##### 4.2.1 Technical Quality of the Product Evaluation Program

During the review period, 111 SS&D actions were performed by the State. The review team selected 15 of these SS&D actions for review. The sample cases represented a broad spectrum of the Branch’s licensees, a range of the various approval functions which the SS&D Unit performs (i.e., new approvals, amendments, inactivations), as well as the span of time between the previous and the present IMPEP reviews. Case specific comments are found in Appendix F.

Review of casework and interviews with the staff confirmed that the Branch follows the recommended guidance from the NRC SS&D training workshops. The registration files contain the correspondence, photographs, engineering drawings, radiation profiles, and results of tests conducted by the applicant. In addition, the SS&D Unit has developed a set of 13 review

checklists since the previous review to assure that all the relevant materials are submitted and reviewed. The checklists are specialized to suit the nature of the applications, (e.g., devices, sources, generally licensed cases, medical use, gamma irradiators, well logging, etc.). The checklists were contained in the registration casework reviewed with minor exceptions. The Branch indicated that the guidance in NUREG-1556, Volume 3, issued July 1998, is utilized for the reviews. All pertinent ANSI Standards, Regulatory Guides, and NRC SS&D training workshop references were confirmed to be available and are used when performing SS&D reviews.

The quality of the Branch's SS&D actions has shown a significant improvement over those reviewed during the previous review. The depth of the technical evaluation has increased and the full scope of the case evaluation has been assured by using a formalized approach. The documentation of the review for permanent records has shown a continual improvement over time. The review team noted a steady trend of improvement in the quality of the SS&D case work over the course of the review period.

No safety issues were identified in the sampled cases. However, some weaknesses were noted. The management of the SS&D program is still not fully formalized. The use of the check lists is transmitted to the staff by oral instructions and no formalized procedures are used. The SS&D Unit has not updated a management procedure which was issued in 1995 (RML-89-1, dated March 1, 1995) and found inadequate in the previous IMPEP review.

The use of the check lists were inconsistent. In some cases, both of the reviewers filled out separate check lists, but in other cases they used double check marks on one list. Some files contained a check list entitled "Registration Certificate Check for Completeness" while others did not.

The SS&D Unit has no formal or oral procedures to handle proprietary information. Presently, documents marked by applicants as proprietary are placed in the same file as all the other documents. In some cases, this information may be proprietary, but in one case an operating manual sent to the user of a device was improperly stamped as proprietary.

Some correspondence practices lead to loss of information needed to trace the basis for issuing an amendment or certificate. Specifically, outgoing letters refer to enclosures without specifying it by title or date, or having it attached to the file copy of the letter. Consequently, such items as a list of deficiency questions or a specific amendment of a certificate cannot positively be traced.

As discussed in Section 2 of the report, the team noted that the SS&D Unit still has not updated a management procedure issued in 1995. The quality of the SS&D evaluation is based on the personal experience of senior SS&D staff and not formally documented. For example, the team noted that adoption of 10 CFR 30.32(g) and 10 CFR 32.210 by legally binding requirements was not consistently implemented by the SS&D staff as a result of the failure to notify two reviewers of the change. The team recommends that the SS&D Unit formalize procedures for the review of applications, particularly the proper use of checklists, handling of proprietary information, full control of records, incorporating regulations and policies as legally binding requirements, and the requirement for signatures by two qualified reviewers.

#### 4.2.2 Technical Staffing and Training

Presently, the SS&D Unit leader and three staff members conduct reviews. Two of the three staff members have conducted only one and two reviews respectively. These individuals have not attended the SS&D workshops sponsored by NRC and have only limited experience reviewing license applications and SS&D applications. Two other individuals, who have more experience and training, left the SS&D Unit during the review period.

The team found that the SS&D reviewers work informally, with the exception of the check lists, when conducting a review. Both the interviews and the casework indicated that the SS&D Unit leader discusses with the staff members the issues and concerns that are identified in an application. These discussions, which are frequently noted by the SS&D Unit leader's initials in the records, assure the quality of the product. In addition, before issuing an SS&D certificate, the SS&D Unit leader performs a concurrence review as a QA measure.

The review team noted several issues regarding technical staffing and training. The quality of the SS&D reviews is currently maintained by two persons: the SS&D Unit leader and the experienced staff member. Since the application review procedure is not formalized, maintenance of the quality of the SS&D reviews relies entirely on the presence of these individuals. Also, there is no set of formal requirements for training or qualifications to perform SS&D evaluations. Consequently, the quality of the reviews is not assured for the future.

The two staff members with the limited experience have signed the certificates as one of the signatories. The minimum number and the types of case work should be formally established before a person is qualified to sign the certificate. The team discussed potential training in the form of actual reviews that could be obtained through working with other SS&D reviewers at the NRC or other Agreement States. The team recommends that the Branch establish formal training and qualification requirements for SS&D reviewers.

The SS&D Unit has a backlog of 60 cases. The volume of the backlog is equivalent to two years of case work at the present rate of completion. Branch management and the SS&D staff explained that this backlog is due to a shortage of staff. The same personnel perform both SS&D reviews and licensing actions. Branch management is currently addressing the backlog by requesting additional staff from the State legislature and reassignment of other personnel. Although the team did not identify any immediate health and safety concerns created by the SS&D backlog, the team expressed their concern regarding both the SS&D and licensing backlog during the exit meeting with Department management.

#### 4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Incidents and defects related to SS&Ds are logged in the data base of "Investigations." (See Section 3.5). During the review period, there were 24 cases related to incidents and defects of SS&D. The team reviewed eight cases. The team selected the sample on the basis of safety significance as it could be judged from the data base listing. A list of SS&D incident files examined along with case specific comments is contained in Appendix E.



The range of subjects varied widely from a radiography source disconnect through a rusted/fallen-off shutter to leaking sources. The Branch handles the investigations of incidents or defects in a highly organized and formal manner. Incident reports are completed, inspections are conducted to follow up the reports, inspection reports document the results of site visits, inspector's notes are included in the file as permanent records and, as a formal completion step in the process, a close out report is prepared for the file. Frequently, the file also contains a chronological summary of the steps that were taken to complete the case. As a final QA measure, the case is closed by a cover sheet completed by the case worker and countersigned by a QA reviewer. The team concluded that evaluation of SS&D defects and incidents are conducted in an exemplary manner.

The review team found that all cases, with one exception, all safety issues were resolved. In one case, the resolution of a safety issue for a particular source had generic implications that the immediate solution did not address. Specifically, a leaking source was resolved by changing the fabrication process. However, the resolution of the particular incident was not followed through, and consequently, the source certificate was not updated to reflect the change in the fabrication process. Thus, the source certificate is outdated and needs to be amended. The team recommends that source certificate CA-406-S-177-S be amended to reflect the change in fabrication process.

Based on the IMPEP evaluation criteria, the review team recommends that California's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory.

#### 4.3 Low-Level Radioactive Waste (LLW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of LLW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLW disposal authority without the need for an amendment. California, an Agreement State since 1962, has LLW disposal authority, and has issued a license to U.S. Ecology to construct and operate a LLW disposal facility at Ward Valley near Needles, California. The land for the Ward Valley site has not been transferred from Federal to State control. California is the host State for the Southwestern LLW compact which includes Arizona, North Dakota and South Dakota.

Prior to start of current State fiscal year on July 1, 1999, the State's LLW program resided in the Department's Division of Drinking Water and Environmental Management. Effective July 1, 1999, the California Legislature no longer funded the LLW program. Subsequently, the Department terminated the program and transferred the three remaining staff members to other programs in the Department.

The team discussed the status of the LLW program with the Assistant Chief in the Division of Drinking Water and Environmental Management. Due to the hold placed on the transfer of the land, the main focus of the LLW program staff during the review period until the program's termination was providing support in responding to challenges to the transfer of the land and the issuance of the license. Regulations promogated in support of the LLW program and its enabling legislation are still in effect. The Department confirmed that if there is a need to regulate an LLW disposal facility in the future, they plan to put a program in place which will meet the criteria for an

adequate and a compatible LLW disposal program. Since California does not have plans for an LLW disposal facility, the review team did not review this indicator.

## 5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found California's performance to be satisfactory for all seven performance indicators. Accordingly, the review team recommended and the MRB concurred in finding the California Agreement State Program to be adequate and compatible with NRC's program. Based on the results of the current IMPEP review, the next full review will be in approximately 4 years.

Below is a summary list of recommendations, as mentioned in earlier sections of the report, for evaluation and implementation, as appropriate, by the State. Also, the "good practices" noted in the report are identified.

### RECOMMENDATIONS:

1. The team recommends that the Branch submit reportable events to NMED within one month of their occurrence in accordance with the "Handbook on Nuclear Event Reporting in the Agreement States." (Section 3.5)
2. The team recommends that the SS&D Unit formalize procedures for the review of applications, particularly the proper use of checklists, handling of proprietary information, full control of records, incorporating regulations and policies as legally binding requirements, and the requirement for signatures by two qualified reviewers. (Section 4.2.1)
3. The team recommends that the Branch establish formal training and qualification requirements for SS&D reviewers. (Section 4.2.2)
4. The team recommends that source certificate CA-406-S-177-S be amended to reflect the change in fabrication process. (Section 4.2.3)

### GOOD PRACTICES:

1. During the MRB, the process for evaluating, analyzing and supporting a change in the inspection frequency for a class of licensees based on performance was deemed a good practice. (Section 3.1)
2. The review team recommends that the use of a QA Health Physicist be found a good practice, specifically for larger radiation control programs. The position strengthens the Division's performance and ensures that health and safety issues are properly addressed. (Section 3.5)
3. The team recommends the regulation readings as a good practice since it provides the technical and administrative staffs, the individuals responsible for implementing the

regulations and those most often in contact with the licensees, the opportunity to identify potential problems before the regulations are finalized. (Section 4.1)

## LIST OF APPENDICES

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APPENDIX A

**IMPEP REVIEW TEAM MEMBERS**

<b>Name</b>	<b>Area of Responsibility</b>
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John Jankovich, NMSS	Sealed Source and Device Evaluation Program
Linda McLean, Region IV	Status of Materials Inspection Program Technical Quality of Inspections Inspection Accompaniments
Lance Rakovan, OSP	Response to Incidents and Allegations
Cynthia Sanders, State of Georgia	Technical Quality of Licensing Actions
Mark Shaffer, Region IV	Inspection Accompaniments

APPENDIX B

CALIFORNIA

DEPARTMENT OF HEALTH SERVICES  
and  
DIVISION OF FOOD, DRUG, AND RADIATION SAFETY  
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**ORGANIZATION CHARTS**

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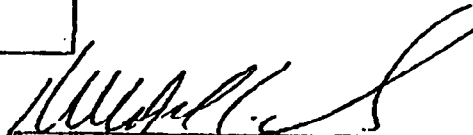
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- 2 Allen Davidson is Acting Chief, Drug Safety Section.
- 3 Jim Bargas is Acting Chief, Medical Device Section.
- 4 Clay Larson is Acting Chief, Food and Drug Laboratory Branch.

  
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December 6, 1999

Mr. Paul H. Lohaus, Director  
Office of State Programs  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

Dear Mr. Lohaus:

We have received and reviewed the draft Integrated Materials Performance Evaluation Program (IMPEP) report enclosed with your letter of November 4, 1999.

We agree with the findings, assessment, and recommendations of the IMPEP review team. We appreciate the opportunity to review and comment on the draft report at this stage of the process. Some minor typological errors of the draft report will be conveyed directly from my staff to Mr. Duncan White, the leader of the IMPEP review team for the California program.

We will be happy to meet with the Management Review Board on this IMPEP review the week of December 20, 1999.

Sincerely,

A handwritten signature in cursive script, appearing to read "James W. Stratton".

James W. Stratton, M.D., M.P.H.  
State Health Officer and Deputy Director  
Prevention Services

cc: Edgar D. Bailey, C.H.P. Chief  
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OSP

SUMMARY OF CALIFORNIA'S COMMENTS  
ON THE DRAFT IMPEP REPORT

In Don Bunn's November 18, 1999 comments to the draft IMPEP report, the following revisions were suggested:

Page 2, Section 2.0, last line of 1. should read:

The Branch is currently developing a written training program similar to "NRC/OAS Working Group Recommendations for Agreement State Training Programs." (See Section 3.34 for more details) This recommendation is closed.

Page 13, Section 3.5, first paragraph on page, last line should read:

The Branch has budgeted sufficient training funds, but staff attendance at training courses outside California is limited during the first four to five months in the State's fiscal year (starts on ~~June~~ July 1) due to State restrictions on out-of-state travel without approval by the Governor's office.

Appendix E, File 3, the location should read:

Location: ~~San Landry~~, San Leandro, CA