August 12, 2004

Richard J. Jackson, MD, MPH
State Public Health Officer
Department of Health Services
P.O. Box 997413
MS-0000
Sacramento, CA 95899-7413

Dear Dr. Jackson:

On July 28, 2004, 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 IMPEP review was conducted April 26-30, 2004. The MRB found the California program adequate, but needs improvement, and not compatible with U.S. Nuclear Regulatory Commission's (NRC's) program. Because of the significance of the findings, the MRB determined the California program should undergo a period of heightened oversight. Heightened oversight is an increased monitoring process used by NRC to follow the progress of improvement needed in an Agreement State program. It involves preparation of a program improvement plan, bimonthly conference calls, and submission of status reports prior to each call with the appropriate California and NRC staffs.

The MRB agreed with the team finding that the underlying root causes of the identified weaknesses are lack of adequate funding and staffing for the program. We appreciate your commitment to the program expressed during the MRB meeting and your efforts to obtain funding and to free up frozen staff positions necessary to operate an adequate and compatible program.

We request that you prepare and submit a program improvement plan as part of your response to the recommendations in Section 5 of the enclosed final report, "Integrated Materials Performance Evaluation Program, Review of California Agreement State Program - Final Report." I ask that you have your staff dialogue with Paul Lohaus on the required elements of this plan to ensure that the "get-well" path and measures of success are clearly identified. The plan should be submitted within 30 days of this letter. Upon review of the program improvement plan, the staff will schedule the first conference call. The initial conference call should be scheduled and conducted no later than October 4, 2004. Based on the results of the current IMPEP review, a follow-up review will be scheduled during the period April 2005 - June 2005. The follow-up review will cover the State's action on the recommendations from the April 2004 review.

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

Sincerely,

/RA/

Martin J. Virgilio
Deputy Executive Director
for Materials, Research and State Programs

Enclosure:
As stated

cc: Kevin Reilly, DVM, Prevention Services
Larry Barrett, DVM, Division of Food, Drug & Radiation Safety
Edgar Bailey, Chief, Radiologic Health Branch
Clayton Bradt, NY, OAS Liaison to the MRB

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bcc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF CALIFORNIA AGREEMENT STATE PROGRAM

April 26-30, 2004

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 of April 26-30, 2004, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement States of Texas and Arkansas. 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 February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period October 9, 1999 to April 30, 2004 were discussed with California management on April 30, 2004.

A draft of this report was issued to California for factual comment on May 28, 2004. The State responded in a letter dated July 1, 2004. At the time of the review, the team found California's performance satisfactory for four performance indicators, and satisfactory, but needs improvement, for the performance indicators, Technical Staffing and Training and Technical Quality of Incident and Allegation Activities. The review team found California's performance to be unsatisfactory for the performance indicator, Compatibility Requirements. Because of the significance of the concerns, the team recommended that a period of heightened oversight be implemented to assess the progress of the State in implementing corrective actions.

On July 28, 2004, the Management Review Board (MRB) met to consider the proposed final report with California staff. The MRB agreed with the team finding that the underlying root causes of the identified weaknesses are the lack of adequate funding and staffing for the program. As discussed with California staff during the MRB, California management is committed to the program and are continuing efforts to obtain funding and to free up frozen staff positions necessary to operate an adequate and compatible program. The MRB concurred in the individual findings by the review team for each indicator and concurred in the review team's recommendation for a period of heightened oversight to assess the progress of the State in implementing corrective actions. The MRB found the California radiation control program was adequate, but needs improvement, and not compatible with NRC's program.

The MRB directed that: (1) a program improvement plan should be prepared and submitted as part of the responses to the recommendations found in Section 5; (2) that a follow-up review be conducted during the period April-June 2005; and (3) that bimonthly conference calls take place with California staff, with a written progress report submitted two weeks prior to each call.

The California Agreement State program is located in the Department of Health Services (the Department). Within the Department, the Radiologic 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 Governor's office, the Department, Division and Branch are included as Appendix B. The California program regulates approximately 2,182 specific licenses authorizing radioactive materials. The review focused on the material 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 January 6, 2004. The Department provided a

response to the questionnaire on April 12, 2004. A copy of the questionnaire response may be found on NRC's Agencywide Document Access and Management System using the Accession Number ML041060605.

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 Department's licensing and inspection data base; (4) technical evaluation of selected licensing and inspection actions; (5) field accompaniments of nine 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 State's actions in response to recommendations made following the previous IMPEP review and the team's conclusions regarding close-out of the recommendations. 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 and recommendations. 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 IMPEP review, which concluded on October 8, 1999, four recommendations were made and the results transmitted to James W. Stratton, M.D., Deputy Director, Department of Health Services on January 4, 2000. The review team's evaluation of the current status of the recommendations is as follows:

1. The team recommends that the Branch submit reportable events to Nuclear Materials Events Database (NMED) within one month of their occurrence in accordance with the "Handbook on Nuclear Event Reporting in the Agreement States." (Section 3.5 of the 1999 report)

   Current Status: The Branch improved their reporting frequency since the last IMPEP review, and no longer report events to NMED on a quarterly basis. However, a number of reportable events for the current review period were not submitted within one month of their occurrence. Of the 76 events which the Branch has tracked as being reportable within 30 days, 35 events were reported late. Of these 35 events, 20 were reported more than 60 days after the event. This recommendation remains open and is further discussed in Section 3.5.

2. The team recommends that the Sealed Source and Device (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 of the 1999 report)

   Current Status: The Branch established and implemented several new procedures, RML-04-1, RML-04-02 and RML-04-03, effective March 26, 2004, that address the

above noted areas. The Senior Health Physicist supervising the SS&D evaluation program indicated that Office of State and Tribal Programs (STP) Procedure SA-201 "Review of State Regulatory Requirements" would be followed when incorporating regulations and policies as legally binding requirements. This recommendation is closed.

3. The team recommends that the Branch establish formal training and qualification requirements for SS&D reviewers. (Section 4.2 of the 1999 report)

   Current Status: The Branch has established and implemented the Licensing Projects Unit Training Journal system, effective date October 21, 2002, for documenting training and qualification requirements for SS&D reviewers. The review team's evaluation of this document identified an effective training tool, as detailed in Section 4.2. This recommendation is closed.

4. The team recommends that source certificate CA-406-S-177-S be amended to reflect the change in fabrication process. (Section 4.2 of the 1999 report)

   Current Status: On February 20, 2001, the Branch issued an 'amendment in entirety' to the above-cited SS&D sheet appropriately addressing the change in the fabrication process. This recommendation is closed.

In addition to the above recommendations, a recommendation from the 1996 California review was re-evaluated. The issue was closed during the 1999 IMPEP review, but the review team observed that all corrective actions had not been completed. The recommendation was:

> 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 of the 1996 report)
>
> Current Status: The team determined that the Branch has been addressing this issue with the licensee to revise the SS&D sheet for QA/QC issues and reissue under current SS&D format as a distribution to specific licensees only. A deficiency letter was issued to the licensee in 2002. The manufacturer's response was that the licensee had not produced this model in several years and wanted to inactivate the SS&D sheet. The Branch is still working with the licensee to gather the information necessary, per NUREG-1556, Volume 3, "Applications for Sealed Source & Device Evaluation and Registration," to inactivate the SS&D sheet. In the State's July 1, 2004 response to the draft IMPEP report, the Branch indicated that they contacted the licensee on June 14, 2004. The licensee stated that they still plan to deactivate the SS&D for the device in question and would submit the appropriate information. In the interim, the Branch will evaluate and administratively amend the SS&D to support distribution to specific licensees only. This recommendation remains open.

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) Technical Staffing and Training; (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Branch's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Branch's questionnaire responses relative to this indicator, interviewed Branch management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

The Branch has four Sections, all reporting to the Branch Chief. The Financial Operations and Analysis Section serves the program infrastructure. The Registration, Certification, Mammography and Standards Section deals primarily with machine-made radiation. The Radioactive Materials Licensing Section performs all of the Agreement State licensing functions. The Inspection, Compliance, and Enforcement (ICE) Section is the inspection arm of the Branch.

The ICE Section is operated out of the Sacramento office and four regional offices, in Berkeley, Granada Hills, Brea and San Jose. Each of the offices has a Senior Health Physicist with seven Associate Health Physicists spread amongst the offices. In addition, the Branch has contracts with Los Angeles and San Diego Counties to perform radioactive material inspections. Five radioactive materials positions are currently employed by the County programs. The total number of health physicist positions in the ICE Section is currently 17, two less than in 1999.

The Radioactive Materials Licensing Section employs four Senior Health Physicists, 20 Associate Health Physicists and four support staff. All of the Branch licensing functions are performed in the Sacramento office. The Regulations Unit reports directly to the Branch Chief and is staffed by a Senior Health Physicist, an Associate Health Physicist and two Analysts.

Approximately 50 positions in the Branch are predominantly dedicated to the radioactive materials program. As the Branch also regulates the use of machine-made radiation, some positions are shared between program areas. The Branch is staffed with a Branch Chief, an Assistant Branch Chief, four Section Chiefs, a technical assistant to the Branch Chief, health physics staff and administrative support staff. Three of the four Section Chief positions are currently vacant, with senior staff filling the positions in an acting capacity. The Assistant Branch Chief is also acting in that position.

The non-permanence of Branch supervisors is due to a current State-mandated hiring freeze and promotion prohibition policy. The Branch Chief noted that, with rare exceptions, the Branch is not authorized to hire or promote individuals because of the severe financial condition of the State. An additional burden for the Branch is a longtime State practice in which a position, if vacant for a period of six months, is abolished. Thus, a "Catch-22" is created when the Branch loses an employee to retirement or outside employment and the position is abolished, as another individual cannot be promoted into that position, nor can an individual be hired to fill the

position or an acting employee's position. These limitations have resulted in most of the Branch management in acting positions as Section Chiefs along with their own Senior Health Physicist responsibilities. In addition, several other technical positions were lost due to the "Catch-22" situation that has resulted in a program staffing shortage. The staffing shortage has impacted the Branch performance in most program areas as discussed in this report.

During the last IMPEP review in 1999, California was commended for a "good practice" for establishing a Quality Assessment (QA) Unit in the ICE Section. When innovative and effective practices are identified during IMPEP reviews, the NRC shares these "good practices" with all Agreement States and NRC Regional Offices. The 1999 IMPEP team commented on the positive effects of the QA Unit in improving the quality of the Branch's inspection and incident response efforts. Health Physicists in the QA Unit developed policies, performed audits of inspections and incident follow-up actions, and emphasized consistency among the seven program offices. The positions in the QA Unit were abolished during the review period when vacant positions were not filled due to the hiring limitations identified above. Some of the QA duties were assumed by a senior health physicist. However, this staff member was not assigned these duties on a full-time basis, which has resulted in significant delays in QA reviews. Issues identified in Section 3.5, "Technical Quality of Incident and Allegation Response Activities," clearly show the quality gap created when the QA Unit was disbanded.

The California radiation control program is in critical financial condition. Branch managers shared with the review team budget revenue and expenditure data which shows a continuous negative budget trend. Efforts to increase licensee fees have been pursued for the last five to six years, with no success. With revenues not increasing to meet increased program costs, financial reserves are being exhausted. The review team believes that the overall root cause of the program deficiencies identified during this review is the critical financial condition of the program. A significant contributing factor is the inability of the Branch to update their fee system to reflect the actual costs of the radiation control program. Without an increase in the program's fee system, the Branch is projected to face insolvency in late 2004 or early 2005. The review team recommends that the State ensure that adequate resources, both funding and staffing, be devoted to the radiation control program.

The Branch's training policy for inspectors is contained in the ICE Section manual. Inspectors are permitted to perform inspections for those categories of licenses for which training has been received. An inspector qualification matrix was shared with the team during the review. The team did not identify any instances in which an inspection was performed by an unqualified inspector. Qualifications for license reviewers are not formally documented, with the exception of the SS&D staff (see Section 4.2.2). Discussions with the Acting Licensing Section Chief and Senior Health Physicists indicated, however, a good awareness of training history and needs of Licensing staff. The review team found that the excellent peer review and training techniques observed during the review constituted an adequate training program.

Due to current budget limitations, outside training for Branch staff has been sharply curtailed. This limited training budget, along with out-of-State travel restrictions, will, in the future, severely limit the ability of the program to maintain a technically trained staff. Even in-State travel faces impediments. All overnight travel by Branch staff must be approved at a Divisional level. This added burden makes it difficult to arrange for training at universities or manufacturers, or even in Sacramento for those staff located in Southern California.

With the current inability to send staff to out-of-state NRC-sponsored training courses, the Branch is looking to import courses into the State. In September 2003, an SS&D Workshop was held in Los Angeles. The review team encouraged the Branch to look for other opportunities to bring training to California and to work with neighboring States to share training efforts. Many of the NRC-sponsored training courses are "portable" and can be held in a State if the State can host the course and guarantee that at least one-half of the student slots are filled.

The review team discussed the role of the Nuclear Medicine Council with Branch managers. The Council serves as an advisory committee to the Branch for advice on nuclear medicine issues and increases opportunities for communication within the regulated community. The Council met last in early 2003. No evidence of any conflict of interest issues was identified.

As noted above, the overall root causes of the program weaknesses identified during this review are the lack of adequate funding and staffing for the program. This has placed the program under stress and the Branch cannot continue to operate under these conditions without experiencing additional performance shortfalls. 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, but needs improvement.

3.2 Status of Materials Inspection Program

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

As previously mentioned, the Branch has contracts with Los Angeles and San Diego Counties to perform radioactive material inspections. County employees can only inspect licensees that have all of their licensed operations in that County. Therefore, an industrial radiographer could not be inspected by the County for temporary jobsites since the license would allow use of radioactive materials at temporary jobsites outside of County jurisdiction.

In April 2004, the Branch adopted the inspection frequencies for various types of material licenses listed in NRC Manual Chapter (MC) 2800, "Materials Inspection Program," under "Emerging Technologies." This change in frequencies was in reaction to NRC's inspection frequency modifications in October 2003. The staff uses a database management system for tracking inspections. The information is compiled monthly in a special report and sent to the inspection field offices. All inspectors have access to these monthly reports. The review team verified that inspection intervals for various types of material licenses are as frequent as, or more frequent than, similar license types listed in MC 2800.

In their response to the questionnaire, the Branch indicated that no routine inspections were overdue by more than 25 percent of the NRC frequency at that time. The Branch also indicated that in the first half of 2001 they discovered a defect in a newly implemented inspection scheduling system that caused 51% of the inspections completed during that period to be overdue. Aggressive steps taken by the Branch to address the problem resulted in the

percentage of overdue inspections to go down to 45% during the second half of 2001, down to 35% during the first half of 2002, and down to 6% by the end of 2002. Since then, the percentage of overdue inspections has fully met IMPEP performance criteria.

The review team noted that two portable gauge licensees could not be located and have appeared as overdue inspections in the Branch's records for approximately two years. The team also noted that two medical facilities had gone out of business, one a boarded up building and the other a building undergoing renovations by the new owner. Upon assessment of the team's concerns, the Branch determined that one of the medical facilities was authorized to possess only accelerator-produced radioactive isotopes, and was thus beyond the scope of this IMPEP review. The team determined that the Branch has not been able to account for the whereabouts of the materials possessed under three licenses, and that the Branch did not appear to have a process in place to resolve these types of situations. On May 6, 2004, the NRC provided the State early written notification of this issue, given its significance. A copy of the State's July 8, 2004 response to this notification is attached. The review team recommends that the Branch enhance its ability to account for the whereabouts and security of licensed materials known to have existed under a license.

With respect to initial inspections of new licensees, the review team analyzed the Branch process for ensuring that new licensees are inspected within one year of license issuance. Monthly inspection due date reports are distributed to regional offices and are tracked to ensure timely completion. The review team confirmed that initial inspections were performed as required through review of inspection records and by verification with Branch staff.

The timeliness of the issuance of inspection findings was evaluated during the inspection casework review. Of the 39 inspection reports reviewed, nine showed that correspondence transmitting the inspection findings to the licensees were issued greater than 30 days from the completion of the inspection. No special circumstances to justify the delays were noted in any of the nine late reports which ranged from 32 to 99 days post inspection. A list of the inspection reports reviewed is provided in Appendix C. The Branch reviewed the incidence and significance of the late reports and determined that there was no impact on health and safety because of the lateness. The review team recommends that the Branch implement procedures to ensure inspection findings are issued to licensees within 30 days of the completion of routine inspections.

During the review, the team determined that the Branch met and exceeded NRC's current criteria of inspecting candidate licensees (inspection Priorities 1, 2 and 3) operating under reciprocity as specified in NRC MC 1220. From 2000 to 2003, the Branch inspected twenty-nine of seventy-nine reciprocity licensees. The Branch also inspected approximately 20-25% of portable gauge and device reciprocity licensees entering the State.

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

3.3 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 39 radioactive material inspections conducted during the review period. The

review included casework from all of the materials inspectors and several supervisors, and covered inspections of various types including medical therapy, industrial radiography, mobile high dose-rate remote afterloaders (HDRs), and nuclear medicine. Particular attention was given to industrial radiography inspections as the team was aware of the lack of the two-person rule requirements in the California regulations and a reliance by the Branch on office inspections rather than field inspections of radiographers. Appendix C lists the inspection casework files reviewed for completeness and adequacy, with case-specific comments.

Nine Branch inspectors (including three County employees) were accompanied during inspections by review team members in late 2003 and early 2004. Inspector accompaniments were conducted during inspections as follows: a pool irradiator; two industrial radiographers; a medical institution with brachytherapy; a nuclear pharmacy; two research and development laboratories; and two nuclear medicine programs. These accompaniments are identified in Appendix C. During the accompaniments, the Branch inspectors demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were well trained, 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.

Information available in the inspection reports revealed that only six out of 26, or approximately 23%, of radiography inspections included a field inspection. One of the six field inspections performed was requested by an IMPEP reviewer who was accompanying the inspector as part of this review. This is significantly lower than the 50% field review required by the Branch's procedure, especially when reports document that field work is done by licensees on a routine basis. The review team and Branch managers discussed the value that field inspections add to the inspection program. Branch management agreed to the benefits of increasing the percentage of field radiography inspections conducted by the Branch, given that opportunities to complete radiography field inspections are available.

Regarding supervisory inspector accompaniments, the team noted that the majority but not all inspector accompaniments were performed annually. Of the 13 staff members currently assigned to inspection positions, four had not been accompanied on an annual basis. Review team members, however, accompanied all of the inspectors that had not been accompanied by supervisors during the past year. The team and the Branch discussed the value of tracking supervisory inspector accompaniments to ensure they are performed in a timely manner.

The review team determined that the Branch has an adequate supply of survey instruments to support the current inspection program. Appropriate, calibrated survey instrumentation such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers, and micro-R meters were noted to be available. The instruments are calibrated at least annually by a commercial calibration service. The Department's Sanitation and Radiation Laboratory provides support to the program through radiological analyses of samples taken by inspectors during inspections.

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.

3.4 Technical Quality of Licensing Actions

The review team interviewed license reviewers, evaluated the licensing process, and examined licensing casework for 26 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of the license conditions, and overall technical quality. The casework files were also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. 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 which were completed during the review period. The sampling included the following types: academic, medical, nuclear pharmacy, veterinary, industrial radiography, irradiator, decommissioning, gauge, and in-vitro laboratory. Licensing actions reviewed included three new licenses, including one financial surety document, four renewals, five terminations, and fourteen amendments. A listing of the casework licenses evaluated with case-specific comments may be found in Appendix D.

All licensing actions are performed in the Sacramento office by the Radioactive Materials Licensing Section. The Section includes the Medical Unit, the Industrial & General Licensed Device Unit, and the Sealed Source & Devices Unit/Financial Surety Unit.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and inspectable. Deficiency letters clearly state regulatory positions, are used at the proper time, and identify deficiencies in the licensees' documents.

In the Medical Licensing Unit, the Senior Health Physicist assigns licensing actions each Monday to the license reviewers. The license reviewers in the Industrial & General Licensed Device Unit select licensing actions daily from an updated printout of pending actions. The status of all licensing actions is tracked with a database. The Licensing Section generates licenses and correspondence with standardized conditions and formats. Each action is reviewed by a peer reviewer as well as the Unit’s Senior Health Physicist, who signs the licensing actions. The Medical Unit has developed multiple licensing guides based on the NUREG-1556 series as well as licensing guidelines for emerging technologies. The Licensing Units issue a complete license for each licensing action.

In late 2000, license terms were extended for three years, changing the seven-year expiration to a ten-year term. A complete renewal application is required to be submitted every ten years to maintain current information in the files. The general staffing shortage in the Branch has affected the ability of the Licensing Section to keep current with incoming licensing casework and a large backlog of license renewals has occurred. The Licensing Section currently has a backlog of 75 renewals submitted in 2004 and 54 renewals received prior to this year. The review team did not identify any health and safety impact caused by the backlog of licensing actions.

The Licensing Units review each inspection file prior to reviewing renewal applications to determine the inspection and enforcement history of the licensee. However, the review team noted that the lack of a tracking system and unavailability of incident and allegation files in the Sacramento office has directly impacted the Licensing Unit's ability to review a licensee's complete history. The review team recommends that the incident and allegation history of a licensee be reviewed during evaluation of licensing actions.

Decommissioning actions involving licensees removing a building or location of use were reviewed. The review team found that decommissioning licensing actions were well documented, showing appropriate transfer records or appropriate disposal methods and records, confirmatory surveys, and survey records. Terminated licensing actions were well documented, showing appropriate transfer and survey records. It was noted that due to the rescinding of decommissioning legislation, there has been a processing delay for decommissioning/termination actions. The Licensing Units have made progress in this area since January 2004.

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

3.5 Technical Quality of Incident and Allegation Activities

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 Materials Events Database" (NMED) against those contained in the California files, and evaluated the casework and supporting documentation for 13 material incidents. A list of incident files examined along with case-specific comments is contained in Appendix E. The team also reviewed the ICE Section's response to 15 allegations, including 13 allegations referred to the State by NRC, during the review period.

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, misadministration, damaged equipment, equipment failure, lost/stolen material, and leaking source. While the quality of the incident and allegation activities needs improvement, the team found the program's overall response to incidents and allegations to be adequate to protect public health and safety.

When the Branch is notified of an incident or allegation, a Form 5010, "Matter Requiring Investigation/Inspection," is filled out by the staff member who receives the notification. 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. Once the investigation has been closed out by a manager, a "Materials Investigation Closing Memo" is completed and placed in the investigation file. The investigation is then reviewed by a senior health physicist. The ICE Section has written procedures for handling investigations. The team noted that the QA Health Physicist review of investigations, which was identified as a good practice in the last review, is still the practice; however, the staff member performing these reviews is not assigned QA duties on a full-time basis, resulting in delays in

follow-up actions on issues identified in the review. Completed investigations are reviewed by a Health Physicist, however, due to workload, may be delayed for long periods of time.

The review team evaluated four misadministrations which occurred during the review period, two of which were significant events which constituted Abnormal Occurrences. The investigation file for one of the significant misadministrations could not be located by Branch staff. Branch managers indicated that a comprehensive investigation was performed of the event but the investigation file was somehow lost. The event had previously been reported to the NRC as an Abnormal Occurrence. The other significant misadministration was identified by Branch staff as satisfying the Abnormal Occurrence criteria, but was not reported to the NRC as such. STP Procedure SA-300 "Reporting Material Events," specifies that Agreement States should routinely screen events against the Abnormal Occurrence criteria, and report any potential Abnormal Occurrences to the NRC. The Branch agreed to follow up on this incident and to provide an Abnormal Occurrence report to the NRC. The Branch provided the report to the NRC on May 7, 2004.

The review team noted that a potential root cause of the four misadministrations that were examined was the absence of specific requirements for administrations requiring a written directive. California's regulations do not require a written directive. See Section 4.1, Compatibility Requirements, for further information on this issue.

The State has a reporting requirement for misadministrations involving more than 30 microcuries of iodine-131 and iodine-125 which is less restrictive than NRC's regulations. The State requires that licensees report such incidents within 15 days. The NRC reporting requirement for these types of events is 24 hours. The Branch reports such incidents to the NRC within 24 hours of receipt of the report from the licensee. Compatibility issues associated with this requirement and other regulations may be found in Section 4.1, Compatibility Requirements.

The review team queried the incident information reported to the NMED system for the review period and identified 195 reportable incidents. Of the 195 reportable incidents in NMED, 45 were not complete and additional information needs to be provided to NRC's contractor, the Idaho National Engineering and Environmental Laboratory (INEEL). In addition, 172 of the 195 reportable incidents were not closed in NMED. This is an administrative task, and the Branch agreed to take the appropriate action to close these incidents. The review team recommends that the Branch, in coordination with INEEL, complete and close all reportable incidents in NMED.

The team reviewed records maintained by the Branch which note the date that reportable events are submitted to NMED, and concluded that a significant proportion of events with 30-day reporting requirements are being reported in more than one month. Of the 76 events which the Branch has tracked as being reportable within 30 days, 35 events were reported late. Of these 35 events, 20 were reported more than 60 days after the event. Thus, as discussed in Section 2.0, the recommendation from the previous IMPEP review remains open.

During the review period, 17 allegations were referred to the Branch by the NRC. The team reviewed 13 of these, and also reviewed two allegations reported directly to the Branch. For four allegations referred by the NRC and one allegation reported directly to the Branch, there were no records of disposition, and investigation files could not be located by Branch staff.

Subject matters for the four allegations referred by the NRC included decommissioning, waste burial, nuclear gauges, and leaking devices. The subject matter for the allegation which was reported directly to the Branch was not determined. During the review, the team provided copies of NRC's allegation transmittal letters to the Branch. The Branch committed to properly address these allegations, and coordinate with the NRC as appropriate.

The team's evaluation of the ICE Section's allegation files indicated that prompt and appropriate action was taken in response to the concerns in all but two cases. The team also identified two allegations which should be completed, but remain open. The Branch plans to make confirmatory calls to the licensees, and complete their investigations. In addition, the team found one inadequate response to an allegation referred by the NRC. Branch management agreed with this conclusion, and is taking follow-up action to better address the allegation. The review team recommends that the Branch establish and implement a system to track incident and allegation investigations to ensure timeliness, proper documentation, appropriate follow up, and closure.

Based on the IMPEP evaluation criteria, the review team recommends that California's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory, but needs improvement.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in evaluating Agreement State programs: (1) Compatibility Requirements; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. California's Agreement does not cover a uranium recovery program, so only the first three non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

California became an Agreement State in 1962. Along with their response to the questionnaire, the State provided the review team with the opportunity to review copies of legislation that affect the radiation control program. The Branch is designated as the State's radiation control agency. Legislative authority to create an agency and enter into an agreement with the NRC is granted in the Radiation Control Law contained in Division 20, Section 7.6 of the California Health and Safety Code. The review team noted that during the 2001-2002 legislative session, two low-level radioactive waste related bills were signed into law and codified into the Radiation Control Law (see Section 4.3). No other legislation affecting the radiation control program was passed since the previous IMPEP review. State legislation is adequate.

4.1.2 Program Elements Required for Compatibility

The Regulations for Control of Radiation, found in Title 17 (Public Health), Division 1, Chapter 5 (Sanitation), Subchapter 4, of the California Code of Regulations apply to all ionizing radiation, whether emitted from radionuclides or devices. 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.

The review team evaluated the Branch's response to the questionnaire, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the NRC STP's Status of State Regulations tracking system.

A review of the State's administrative rulemaking process found that the process takes at a minimum one year (and often longer) after preparation of a draft rule to the final filing with the Secretary of State, after which the rules become effective in 30 days. 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.

Proposed rules are submitted to the Office of Administrative Law for a legal review and to the Legislative Fiscal Office for consideration and approval to proceed with public comment. Public notice of proposed rule revisions is made and a 30 to 45-day public comment period takes place. A public hearing may or may not be conducted. Concurrently, the proposed rules are sent to NRC for a compatibility ruling. After resolution of comments, the final draft rules are sent to the California Register for adoption. Final rules are then sent to licensees and the NRC. California law requires that guides, criteria, manuals, and instruction standards of general application be enforced only as an adopted regulation. The State can adopt other agency regulations by reference, which has been done with respect to the U.S. Department of Transportation (DOT) transportation regulations and the NRC 10 CFR Part 20 radiation protection regulations.

Several NRC amendments pertaining to changes of Title 10 CFR Part 20, "Standards for Protection Against Radiation" were adopted by reference during the review period and became effective on November 14, 2001. These amendments included NRC's "Radiological Criteria for License Termination" rule. This portion of the regulation was challenged in State court by "The Committee to Bridge the Gap, et al." The challenge was successful, and the "Radiological Criteria for License Termination" portion of the regulation was repealed on August 8, 2002. The current standard for decommissioning in California is that a "Reasonable effort has been made to eliminate residual radioactive contamination, if present." The Branch has been prohibited from interpreting this to mean that a licensee must reduce contamination to a level that is "As Low As Reasonably Achievable" (ALARA), and from establishing any numerical decommissioning standard without first performing a California Environmental Quality Act review. The Branch has not begun such a review and is currently terminating licenses on a case-by-case basis.

Since the last IMPEP review, the State has adopted only one amendment. The State's 10 CFR Part 20 equivalent was adopted by reference. There are currently 15 regulations that the State is overdue in adopting and none of these regulations have been started in the State's administrative rulemaking process. Because of the State's inability to adopt regulations in the time frame required by NRC, the team discussed the use of legally binding requirements or adopting regulations by reference as other alternatives. Branch management said that adopting by reference was not easily workable in their process. The team discussed this issue with the Branch's legal counsel and determined that to issue a license with legally binding requirements in lieu of regulations until compatible regulations become effective is defensible, and the Branch has the authority to do this.

The Branch has used license conditions in some cases; however, none have been reviewed by the NRC for compatibility. In fact, absent from the license conditions are sections of rules that the NRC considers health and safety significant and are listed in STP Procedure SA-200, as B or H&S compatibility categories. For example, two important sections from 10 CFR Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," are not covered by license conditions. The first is the requirement for having two qualified individuals present at a location of radiographic operations and the second is the requirement that a radiographer be certified through a radiographer certification program by a certifying entity.

The industrial radiography "two-person rule" is an example of a regulation with direct health and safety implications. It requires the presence of a second trained individual to observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. The Branch is aware of industrial radiography companies, including out-of-state companies, performing radiography in the State using only one trained individual, to reduce operating costs. California is the only jurisdiction in the United States which does not have a two-person rule.

Other excluded parts of the regulations is the required use of written directives and specific procedures for administrations requiring a written directive, as outlined in 10 CFR Part 35, "Medical Use of Byproduct Materials." In Section 3.5 of this report, it was identified that a least four medical events occurred during the review period. The review team believes that a contributing factor in all cases may have been that the licensees are not required to have a written directive and procedures, as required by 10 CFR 35.40, 35.41, or a quality management program with written directives, as required by Superceded Part 35.

Additionally, the Branch reviewed the license conditions that are currently used to address 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators," and found that the conditions do not cover several substantial parts to the regulations. Specifically, the team reviewed the licenses for commitments comparable to the requirements in 10 CFR 36.57, 36.59, 36.63, and 36.83, and found that California does not consistently ensure that all irradiators subject to Part 36 have license conditions incorporated in their license that address all of the requirements.

The review team also noted that the Branch's inspection manual contains an exception to the reporting requirement for medical events that involve more than 30 microcuries of iodine-131 or iodine-125. The exception authorizes a 15-day notification rather than NRC's 24-hour reporting criteria.

The Branch has three rule update packages prepared to go through the first step of their rulemaking process, which is Branch management concurrence. Only one of these packages has been forwarded to the Branch Chief. The three updates are for radiation safety requirements for well logging operations, industrial radiographic operations, and miscellaneous amendments.

The review team concluded the delay in the promulgation of regulations in a timely fashion was due in part by staff turnover which requires the Branch staff to divert their time and efforts to other essential program elements; however, there appears to have been no effort in submitting the developed rule packages into the rulemaking process for some time. The review team recommends that the Branch develop and implement an action plan to adopt NRC regulations in accordance with current NRC policy on adequacy and compatibility.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they are effective. Several of these amendments are designated A, B or H&S compatibility categories. The following 15 regulations are overdue:

- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104) that became effective on January 27, 1992.
- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994.
- "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendment (60 FR 28323) that became effective June 30, 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. The 10 CFR Part 20 portion of this rule was adopted by the State on September 10, 1998.
- "10 CFR Part 71: Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective on April 1, 1996.
- "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 10 CFR Part 20 portion of this rule was adopted by reference in 1998.
- "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.
- "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 63 FR 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, 35, and 36 amendments (63 FR 39777 and 63 FR 45393) that became effective on November 26, 1998. The 10 CFR Part 20 portion of this rule was adopted by reference in 1998.

- "Respiratory Protection and Controls to Restrict Internal Exposure," 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55524) that became effective February 2, 1999.

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR 20337) that became effective on May 17, 2000.

- "New Dosimetry Technology," 10 CFR Parts 34, 26, and 39 amendments (65 FR 63750) that became effective on January 8, 2001.

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 rulemaking or by adopting alternate legally binding requirements:

- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendments (67 FR 20250) that became effective on October 24, 2002.

- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, and 70 amendments (68 FR 57327) that became effective on December 3, 2003.

Based on the IMPEP evaluation criteria, the review team recommends that California's performance with respect to the indicator, Compatibility Requirements, be found unsatisfactory.

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

In assessing the California SS&D evaluation program, the review team examined the information provided in response to the IMPEP questionnaire. The team evaluated SS&D registry sheets issued during the review period, and the supporting document files. The team also evaluated SS&D staff training records, certain reported incidents involving products authorized in California SS&D sheets, the use of guidance documents and procedures, and interviewed the staff currently conducting SS&D evaluations.

Three sub-indicators were used to evaluate the Division's performance regarding SS&D evaluation. These sub-indicators were: (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation Program; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

4.2.1 Technical Staffing and Training

Presently, the Senior Health Physicist is in charge of the SS&D evaluation program and five staff members conduct reviews. Two of the five staff members have conducted only one review. These individuals have been conducting SS&D evaluations for less than a year and are considered to be in training. Five previously fully qualified and experienced SS&D reviewers left the SS&D evaluation program during the review period. Most of the SS&D reviews completed during the review period were performed by staff no longer in the program.

The review team evaluated the qualifications of the new individuals authorized and currently performing SS&D evaluations. By way of creation of the Licensing Projects Unit Training Journal, formal requirements for SS&D reviewers have been established. All reviewers were deemed qualified by either formal education, completion of appropriate training courses or experience equivalency, except for one reviewer who is lacking the completion of two training

courses. All have regulatory experience and all have attended the NRC SS&D Workshop. Interviews and the casework review indicated that the Senior Health Physicist or the concurrence reviewer, discusses with staff members the issues and concerns that are identified in an application.

Due in part to staff turnover, fees not being assessed for SS&D evaluations, and other pressing licensing functions, such as complex decommissioning and financial assurance, the SS&D evaluation program maintains a backlog of approximately 45 SS&D actions dating back to January 1999, representing, according to interviews, approximately two years' worth of case work. The team did not identify any immediate health and safety concerns created by the SS&D backlog.

4.2.2 Technical Quality of the Product Evaluation Program

The review team evaluated 15 of the 160 SS&D evaluation amendments, inactivations and new registrations the Branch completed during the review period, representing the work of eight SS&D reviewers. The cases were representative of the Branch's licensees and SS&D evaluation personnel completed between October 1999 and February 2004. A list of SS&D files examined along with case-specific comments may be found in Appendix F.

The team's review of the casework and interviews with the staff confirmed that the SS&D reviewers used guidance found in NRC's NUREG-1556, Volume 3, and the American National Standards Institute/ Health Physics Society standards and materials obtained from the most recent SS&D Workshop held in Los Angeles in September 2003. All pertinent ANSI/HPS standards, Regulatory Guides, and applicable references were confirmed to be available and were used when performing SS&D reviews. The appropriate review checklist from NUREG-1556, Volume 3, Appendix C was used to assure relevant materials had been submitted and reviewed. The Branch has augmented the basic Appendix C checklist by creating nine different checklists that address additional information needs based on the proposed use of the product (e.g., well logging sources, radiography equipment, etc.). The checklists were retained in all of the registration files examined and included documentation of second peer or supervisory reviews.

With few exceptions, the registration files contained all correspondence, engineering drawings, radiation profiles, and results of tests conducted by the applicant. The Senior Health Physicist in charge of the SS&D evaluation program related that non-Atomic Energy Act (AEA) material reviews are performed in the same procedural manner using the same references as used for AEA sources and devices. The review team noted that the SS&D evaluation program has, on-staff, two persons with a mechanical engineering degree or equivalent background. During staff interviews it was determined that any product integrity or design parameters not understood by SS&D reviewers will be referred to these individuals for analysis.

In accordance with procedure number RML-04-1, effective March 26, 2004, the SS&D evaluation program handles proprietary information by inserting a colored page before any proprietary or trade secret information. If a request to view SS&D files is received, the Senior Health Physicist will conduct a review of the entire SS&D file to determine if material received prior to the effective date of the procedure contains information considered proprietary or trade secrets.

The registrations clearly summarized the product evaluation to provide license reviewers with adequate information to license the possession and use of the product. Deficiency letters clearly stated regulatory positions and all health and safety issues were properly addressed. The review team determined that the product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and in the event of an accident.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Through self-reporting directly to the SS&D evaluation program and random interoffice notifications, the SS&D evaluation program had collected six events related to SS&D evaluations. The team reviewed four of these cases and identified an adequate response to each. A list of SS&D incident files examined along with case-specific comments may be found in Appendix E.

As in the previous IMPEP, it was determined through staff interviews that there exists no procedure for reporting events associated with SS&Ds to the SS&D evaluation program for follow up. Additionally, there exists no procedure for handling reports of defects and incidents by the SS&D evaluation program. Because of these deficiencies, reports of defects and incidents are not routinely reported to the SS&D evaluation program and appropriate follow-up investigations are delayed and persist for years in some cases. The review team recommends that the Branch formally establish and implement (1) a process to notify the SS&D evaluation program of all defects and incidents involving California administered SS&D sheets; and (2) a procedure for the SS&D evaluation program to investigate reports of defects and incidents for root cause and generic implications for possible subsequent reevaluation of SS&D sheets.

Based on the IMPEP evaluation criteria, the review team recommends that California's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) 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 LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although California has such disposal authority, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for an LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate an LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program.

Funding for the California LLRW program ceased in 2002. Also, in 2002, two LLRW-related State laws were passed prohibiting the development of an LLRW site at Ward Valley, the only location in California licensed for the development of an LLRW disposal facility. There are currently no plans for an LLRW disposal facility in California. Accordingly, the review team did not evaluate this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team and the MRB found California's performance to be satisfactory for four performance indicators, and satisfactory, but needs improvement, for the performance indicators, Technical Staffing and Training and Technical Quality of Incident and Allegation Activities. The review team and the MRB found California's performance to be unsatisfactory for the performance indicator, Compatibility Requirements. Accordingly, the review team recommended and the MRB concurred in finding the California Agreement State program adequate, but needs improvement and not compatible with NRC's program. The review team recommended and the MRB concurred that a period of heightened oversight be implemented to assess the progress of the State, including preparation of a program improvement plan, bimonthly conference calls, status reports before each call, and a follow-up IMPEP review in one year.

Below is a summary list of recommendations, as mentioned in earlier sections of the report, for evaluation and implementation by the State. Included is one open recommendation from the 1999 IMPEP report and one open recommendation from the 1996 IMPEP report:

RECOMMENDATIONS

1. The review team recommends that the State ensure that adequate resources, both funding and staffing, be devoted to the radiation control program. (Section 3.1)

2. The review team recommends that the Branch enhance its ability to account for the whereabouts and security of licensed materials known to have existed under a license. (Section 3.2)

3. The review team recommends that the Branch implement procedures to ensure inspection findings are issued to licensees within 30 days of the completion of routine inspections. (Section 3.2)

4. The review team recommends that the incident and allegation history of a licensee be reviewed during evaluation of licensing actions. (Section 3.4)

5. The review team recommends that the Branch, in coordination with INEEL, complete and close all reportable incidents in NMED. (Section 3.5)

6. The review 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) (Open recommendation from Section 5.0 of the 1999 report)

7. The review team recommends that the Branch establish and implement a system to track incident and allegation investigations to ensure timeliness, proper documentation, appropriate follow up, and closure. (Section 3.5)

8. The review team recommends that the Branch develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 4.1)

9. The review team recommends that the Branch formally establish and implement (1) a process to notify the SS&D evaluation program of all defects and incidents involving

California administered SS&D sheets; and (2) a procedure for the SS&D evaluation program to investigate reports of defects and incidents for root cause and generic implications for possible subsequent reevaluation of SS&D sheets. (Section 4.2)

10. 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 2.0) (Open recommendation from Section 4.2 of the 1996 report)

LIST OF APPENDICES AND ATTACHMENT

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
James Lynch, Region III	Team Leader Technical Staffing and Training Inspector Accompaniments
Linda McLean, Region IV	Compatibility Requirements Inspector Accompaniments
Hector Bermudez, Region II	Status of Materials Inspection Program Technical Quality of Inspections
Andrew Mauer, STP	Technical Quality of Incident and Allegation Activities
Kim Wiebeck, Arkansas	Technical Quality of Licensing Actions
David Fogle, Texas	Sealed Source and Device Evaluation Program

APPENDIX B
CALIFORNIA ORGANIZATION CHARTS

ADAMS ML041260427

GOVERNOR ARNOLD SCHWARZENEGGER

S. KIMBERLY BELSHÉ, SECRETARY
HEALTH AND HUMAN SERVICES AGENCY

SANDRA SHEWRY, DIRECTOR
DEPARTMENT OF HEALTH SERVICES

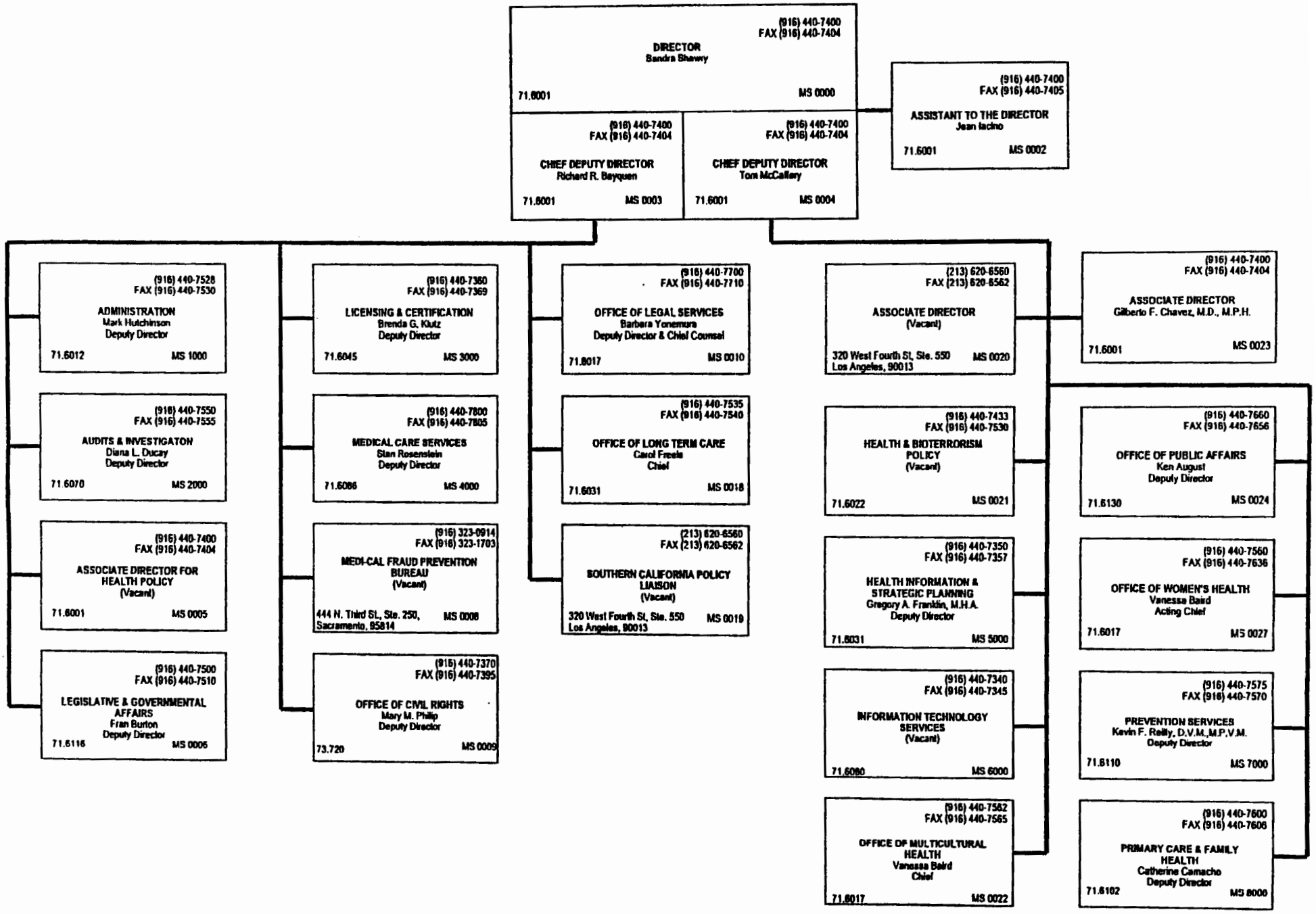
TOM MCCAFFERY, CHIEF DEPUTY DIRECTOR
DEPARTMENT OF HEALTH SERVICES

KEVIN REILLY, DVM, MPVM, DEPUTY DIRECTOR,
PREVENTION SERVICES

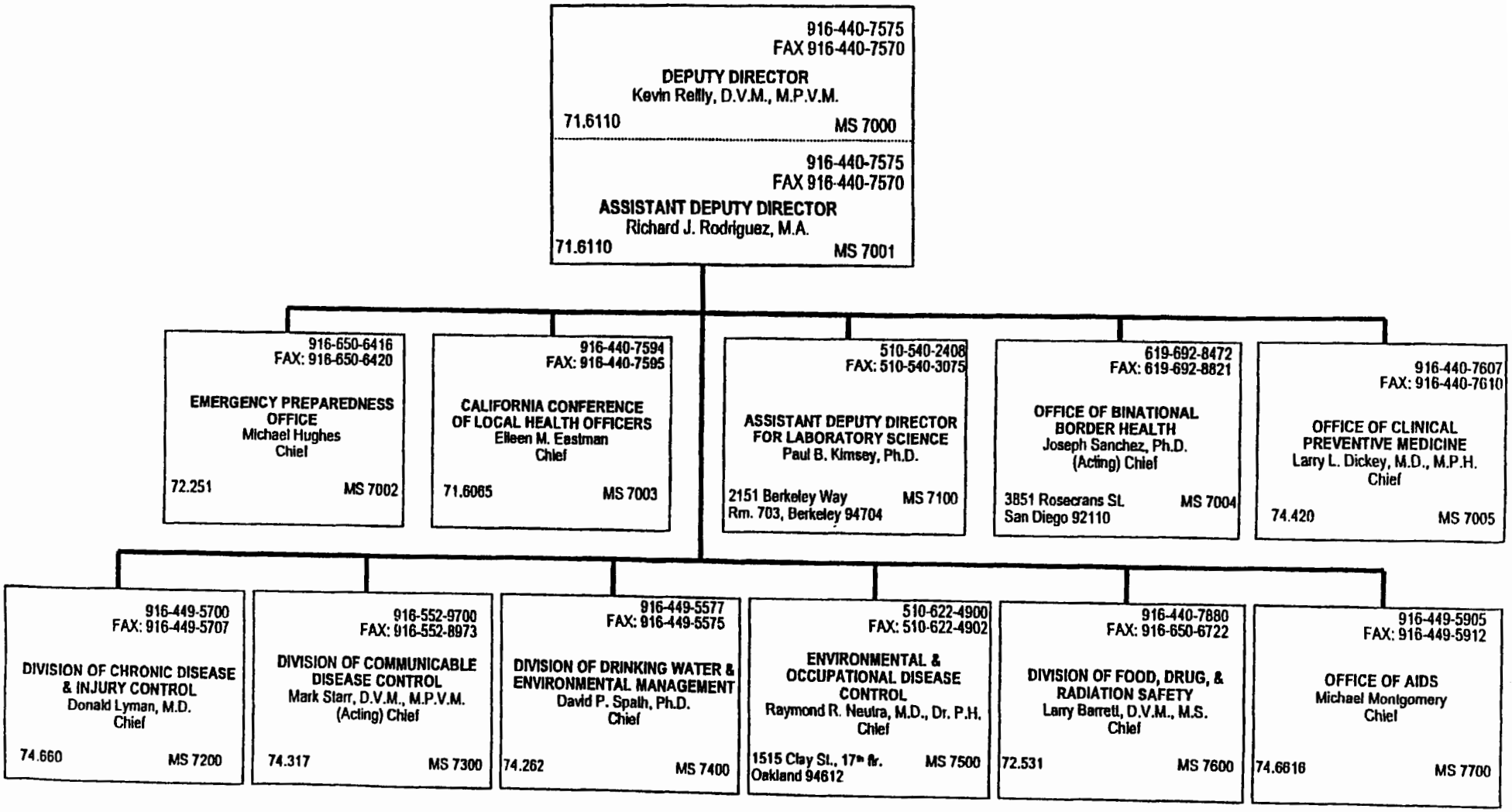
LARRY BARRETT, DVM, MS, DACVPM, CHIEF
DIVISION OF FOOD, DRUG AND RADIATION SAFETY

EDGAR D. BAILEY, CHP, PE, CHIEF
RADIOLOGIC HEALTH BRANCH

CALIFORNIA
DEPARTMENT OF HEALTH SERVICES

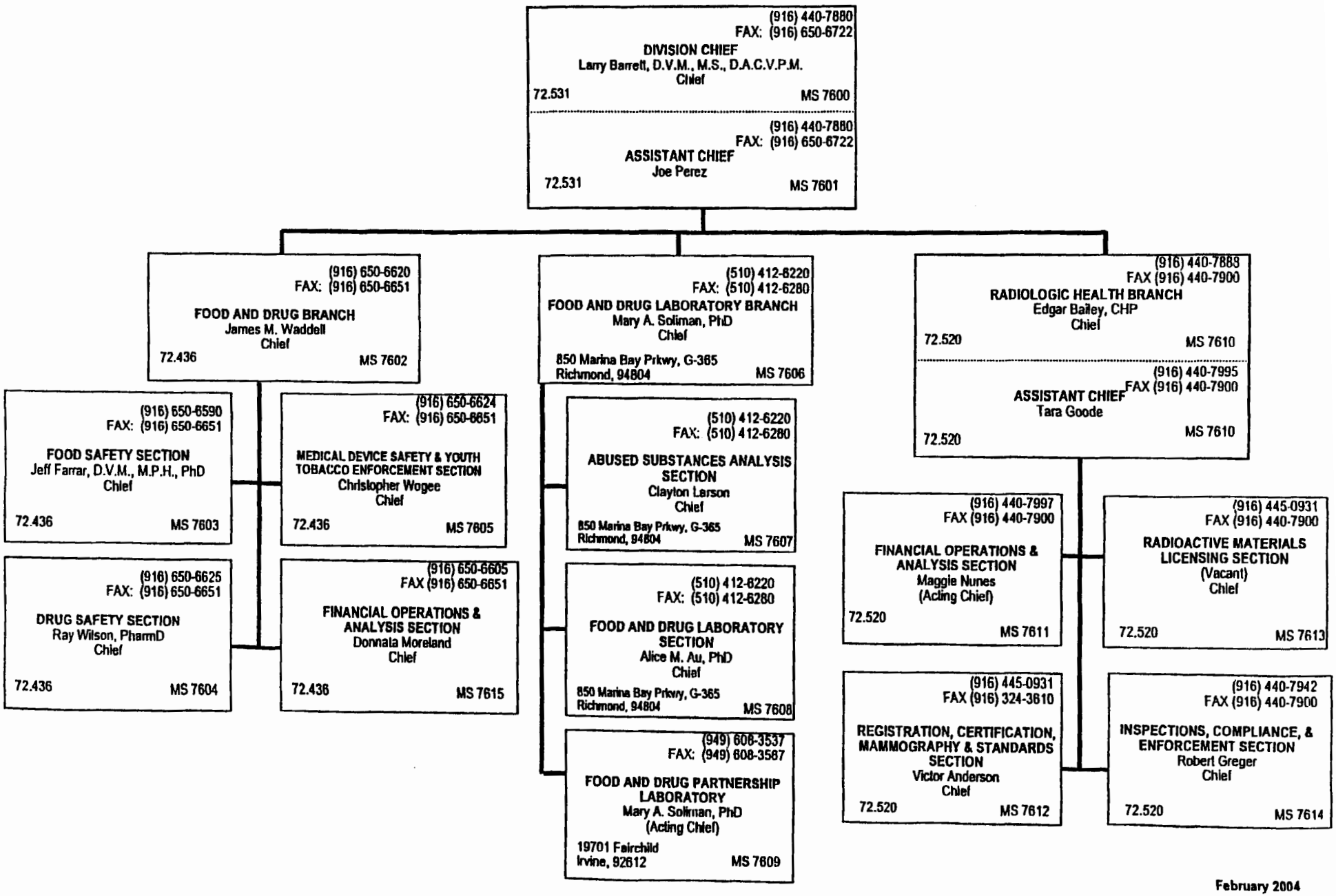


CALIFORNIA DEPARTMENT OF HEALTH SERVICES
PREVENTION SERVICES



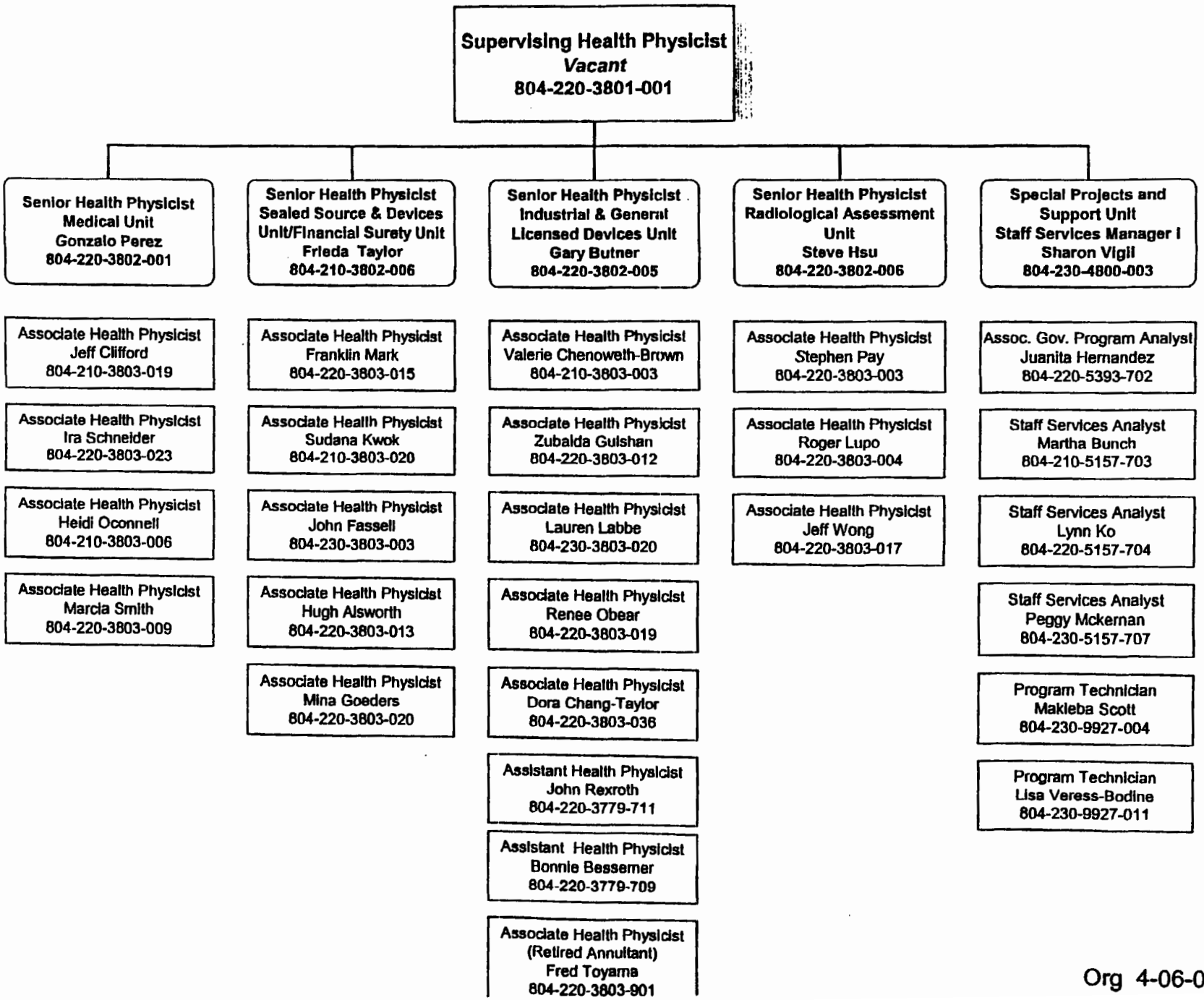
January 2004

CALIFORNIA DEPARTMENT OF HEALTH SERVICES
PREVENTION SERVICES
DIVISION OF FOOD, DRUG, AND RADIATION SAFETY



February 2004

Radioactive Materials Licensing Section



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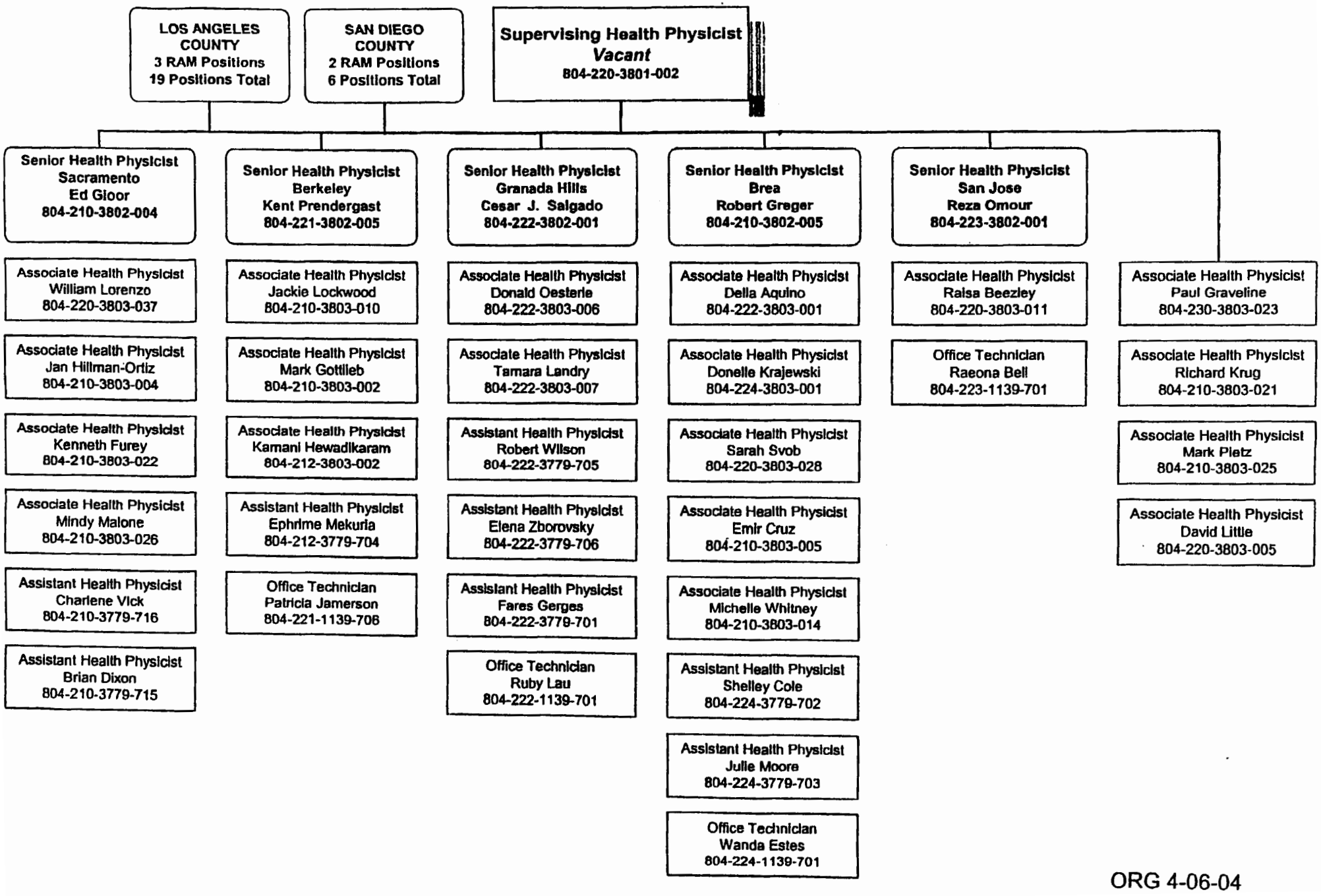
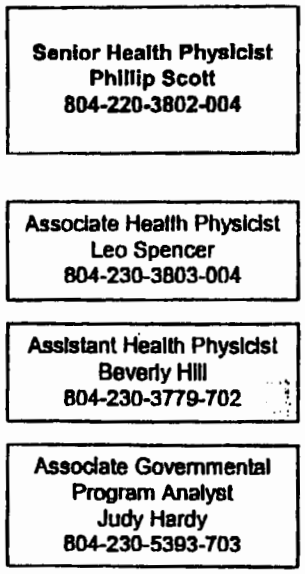
Inspection, Compliance and Enforcement Section



ORG 4-06-04

Regulations Unit



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ATTACHMENTS

July 1, 2004 Letter from Richard J. Jackson
California's Response to the Draft IMPEP Report
ADAMS ML041960580

July 8, 2004 Response from Edgar D. Bailey
California's Response to NRC's May 6, 2004 Letter
ADAMS ML042110327

State of California—Health and Human Services Agency
Department of Health Services

California Department of Health Services
Sandra Shewry
Director

ARNOLD SCHWARZENEGGER
Governor

July 1, 2004

Mr. James L. Lynch
State Agreements Officer
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road
Lisle, IL 60532

DRAFT IMPEP REPORT

Dear Mr. Lynch:

The California Department of Health Services (DHS) has reviewed the Integrated Materials Performance Evaluation Program (IMPEP) draft report provided to us May 28, 2004. We would like to thank you and the entire IMPEP team for your comprehensive review of our Agreement State programs.

DHS is committed to conducting a quality Radiation Safety program, which complies with all the Nuclear Regulatory Commission (NRC) requirements and also protects public health and safety. Please find attached our comments and recommendations on the draft IMPEP report.

Thank you again for your time and efforts related to the evaluation our radiological health program, and for the constructive comments provided in this regard. We look forward to discussing all the issues raised by your review in further detail in July.

Sincerely,

Richard J. Jackson, MD, MPH
State Public Health Officer

Enclosure

cc: Mr. Paul Lohaus
U.S. Nuclear Regulatory Commission
Office of State and Tribal Programs
Washington, D.C. 20555

Technical Staffing and Training

No comments.

Status of Materials Inspection Program

In paragraph 3 of this section, the third and fourth sentences state, "The staff uses a database management system for tracking inspections. The data is maintained on a network and is available to all staff." This is not entirely accurate. The data is maintained in a database management system, but is *not* available on the network to all staff, without a specific request for authorization from the Senior Health Physicist. The information is compiled monthly in a special report and sent to the inspection field offices. All inspectors have access to these monthly reports. The monthly reports are considered adequate to identify inspections that need to be performed to minimize overdue inspections.

In paragraph 5 of this section, the report refers to four licensees that could not be located. One of these licensees was authorized to possess only cobalt-57, an accelerator-produced radioactive isotope, not regulated pursuant to the Atomic Energy Act, but rather pursuant to the State's police powers. Details regarding the status of the other licensees referenced in this section are addressed later in this document under the summary.

In paragraph 7 of this section, the report discusses the timeliness of the issuance of inspection reports. In response to comments made during the on-site IMPEP review, and the discussion in the draft IMPEP report, the Radiologic Health Branch (RHB) reviewed the incidence and significance of the "late" reports, and concluded that there was no impact to health and safety in this regard. The details of our review are included later in this document under the summary. We respectfully request that this section of the report be amended to note that there were no health and safety impacts associated with the "late" reports cited in the draft IMPEP report and its appendices.

Technical Quality of Inspections

No comments.

Technical Quality of Licensing Actions

In paragraph six of this section, the last sentence states, "The Licensing Units are currently reviewing renewals received in 2004." This statement is not totally accurate. The Licensing Units currently have 75 renewals submitted in 2004 and 54 renewals submitted prior to 2004 pending.

Technical Quality of Incident and Allegation Activities

In paragraph three of this section, the last sentence states, "The team noted that the QA Health Physicist review of investigations, which was identified as a good practice in the last review, is no longer in practice, and the position has since been dissolved." This is not entirely accurate. The position has been dissolved, but there is still a QA Health Physicist review of the closed investigations. Due to the fact that the staff member performing these reviews is not assigned to QA duties on a full-time basis, the reviews are often delayed for long periods of time, and follow-up actions on issues identified in the review are not always completed in a timely manner.

In paragraph four of this section, the last sentence states, "The Branch agreed to follow-up on this incident and to provide an Abnormal Occurrence report to the NRC." That report was provided to the NRC on May 7, 2004.

Legislation

No comments.

Sealed Source and Device (SS&D) Evaluation Program

No comments.

Low-Level Radioactive Waste (LLRW) Disposal Program

No comments.

Summary

The recommendations from the draft IMPEP report are included below, with the program's preliminary response to each.

1. The review team recommends that the State ensure that adequate resources, both funding and staffing, be devoted to the radiation control program, and that the State's fee system be updated to reflect actual program costs.

Proposed emergency regulations for a fee increase to the regulated community have been developed and are currently being reviewed for a final decision by the Administration. If they are approved they can be implemented as emergency regulations and fees can be increased to meet program-funding needs in State Fiscal Year 2004-05.

2. The review team recommends that the Branch enhance its ability to account for the whereabouts and security of licensed materials known to have existed under a license.

After the on-site IMPEP review, and the receipt of a May 6, 2004, letter from Mr. Paul Lohaus to the RHB on this subject, RHB took steps to review the specific cases that resulted in this recommendation. In two of those cases, a follow-up investigation was performed at the last licensed locations of use, and the sources were located. In one case, they were retrieved and placed into the RHB's radioactive materials storage area. In the other case, they were left on-site, due to the fact that the new tenant was a medical radioactive materials licensee, and was authorized to possess the sources acquired in the property transfer.

With respect to the other two cases resulting in this recommendation, RHB is still following up on locating one of the licensees. The other licensee was authorized to possess a small quantity of non-AEA material, in sealed form, which by this time would have decayed to a negligible value, and the Branch plans to administratively terminate that license, as all efforts to locate the licensee have been unsuccessful.

In addition, RHB reviewed the circumstances surrounding the two events involving the medical sources, and concluded that, in part, the tracking of these licensees and the sources suffered due to a lack of adequate communication between the Licensing Section and the Inspection, Enforcement and Compliance Section, with respect to the licensees' attempts to terminate their license. We are currently reviewing pending termination actions that might lead to similar circumstances to ensure there is adequate continuing communication between the Sections, and with the licensees to minimize the likelihood that facilities are abandoned during the termination process.

3. The review team recommends that the Branch implement procedures to ensure inspection findings are issued to licensees within 30 days of the completion of routine inspections.

RHB plans to implement a tracking system for inspection report issuance to better control the timeliness of inspection report issuance. To help to clarify the significance of this issue, we would like to note that following the on-site IMPEP review, the Branch reviewed the late reports cited in the draft IMPEP report, and found the following:

Region	Number Late vs. Number Reviewed	Average Number of Days Late	Maximum Number of Days Late
2	4/7	36	69
3	1/8	13	13
7	4/7	5	7

The only potentially significant delays occurred in region 2. Those inspection results were reviewed, and it was determined there were no violations, nor items of significant concern contained in those late results; this information was conveyed to the licensee at the end of the inspection. Region 2 staff indicated these results were delayed due to the heavy workload, which required actions with a higher health and safety priority to take precedence over the delivery of these written inspection results. As noted, RHB plans to implement a tracking system for inspection report results to improve compliance with the internal policy to issue these reports within 30 days; however, RHB does not believe there was any health and safety significance to the fact that these reports were delayed.

4. The review team recommends that the incident and allegation history of a licensee be reviewed during evaluation of licensing actions.

It is the policy of the Licensing Section for reviewers to check the compliance file of licensees during the evaluation of an amendment request. To ensure that the most current information on incidents and allegations is also available to the reviewers a new process is implemented.

A copy of the RHB 5010 Tracking Spreadsheet is now available to all reviewers both electronically and in hardcopy formats. The RHB 5010 form is used to track incidents and allegations. To track the RHB 5010, the Inspection Compliance and Enforcement Section (ICE) maintains an electronic spreadsheet. The spreadsheet is updated when new information is received.

RHB will convert the electronic spreadsheet to a database. This will allow information to be searched based on the user specified criteria. This will assist the reviewers by ensuring that the most update information is available.

5. The review team recommends that the Branch, in coordination with INEEL, complete and close all reportable incidents in NMED.

The number of reports that are noted in NMED as "not closed by the State" is not representative of the actual number of investigations that are not closed. This discrepancy is a result of an administrative failure by RHB to provide a clear statement to INEEL saying RHB has closed the investigation when making the final report to INEEL. RHB plans to revise the tracking and reporting system to provide this additional statement to INEEL when making the final report on an investigation. RHB also plans to review all those events currently reported as "not closed by the State" in the NMED database, and request INEEL amend them to show they are closed, as appropriate; however, this action will not be performed in the immediate future, as it is very time-intensive, and RHB cannot afford to divert support staff resources for this purpose at this time.

In addition, on May 3, 2004, RHB staff created a spreadsheet listing the 52 investigations that indicated the NMED record was "not complete." The review of these records and clarification of the additional information necessary to complete the files cannot be accomplished at this time without additional staff. No progress has been made in this regard.

6. The review 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 Agreement States."

RHB will modify its NMED reporting methodology to enhance the timeliness of reporting event information. RHB had been reporting event information after completion of the investigation and documentation phases of event follow-up were completed. RHB will modify the event reporting procedure such that preliminary event reports with available information will be made to NMED within 30 days. The preliminary NMED reports will be modified when additional information is developed.

7. The review team recommends that the Branch establish and implement a system to track incident and allegation investigations to ensure timeliness, proper documentation, appropriate follow-up, and closure.

RHB does have a tracking system for incidents and allegations. As noted in the draft IMPEP report, a significant impediment to better performance in this area is the result of the loss of a staff position that provided oversight of this tracking system. The current tracking system has been modified somewhat to improve its effectiveness, and a staffing increase will be pursued. RHB management will provide additional emphasis to performance in this area, pending the acquisition of additional staff.

8. The review team recommends that the Branch develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility.

RHB agrees that additional diligence is required in this area. Several regulations packages are being prepared for Division review at this time, and it is anticipated they will be delivered to Division for their review and concurrence in July 2004. Once this concurrence is received, the regulations packages will be transmitted to Prevention Services for their review and concurrence. Subsequently, these regulations must be reviewed by the various offices that must have input (e.g., the DHS Office of Legal Services, the DHS Office of Regulations, the Office of Administrative Law, and the Department of Finance, among others), as outlined in the Regulatory Process Map provided as an attachment to our response to the IMPEP questionnaire.

In the interim, RHB hopes to incorporate certain critical elements via Legally Binding Requirements (LBRs) imposed as administratively issued license conditions. As discussed on the telephone with NRC staff on May 13, 2004, RHB intends to administratively amend radiography licenses, medical licenses, and large irradiator licenses, to address certain requirements in Part 34, Part 35 and Part 36 that have not been adopted or enforced in California up to this time. To date one LBR has been drafted. All industrial radiography licenses were amended on July 1, 2004 to incorporate the requirements of the two-man rule as LBRs. We will submit this LBR to the NRC for review.

Also, as noted in the May 13, 2004, phone conversation, RHB has no current plans for adopting regulations compatible with 10 CFR 20, Subpart E, or with 10 CFR 30.36(d).

9. The review team recommends that the Branch formally establish and implement (1) a process to notify the SS&D evaluation program of all defects and incidents involving California administered SS&D sheets, and (2) a procedure for the SS&D evaluation program to investigate reports of defects and incidents for root cause and generic implications for possible subsequent reevaluation of SS&D sheets.

The Branch has not yet addressed this issue.

10. 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.

RHB contacted the licensee again on June 14, 2004. The licensee stated that they still plan to deactivate the SS&D for the device in question and would submit the appropriate information by June 30, 2004.

In the interim, RHB will evaluate and administratively amend the SS&D to support distribution to specific licensees only. The expected date of completion is July 9, 2004.

State of California—Health and Human Services Agency
Department of Health Services

California Department of Health Services

ARNOLD SCHWARZENEGGER
Governor

July 8, 2004

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

Dear Mr. Lohaus:

This letter is written in response to your May 6, 2004 letter regarding the control of radioactive materials at certain California Department of Health Services (DHS) licensed facilities. This issue was raised during the Integrated Materials Performance Evaluation Program (IMPEP) review in April 2004, and involved four licensed facilities whose licensed sites had been vacated prior to a proper accounting of the disposition of all radioactive materials. This issue was also addressed in the comments on the draft IMPEP report, which we provided to Mr. James Lynch, Regional State Agreements Officer, Region III on July 2, 2004.

In summary, in response to concerns expressed after the on-site IMPEP review, DHS took additional steps to locate the licensees who had vacated their sites without prior authorization. In two cases (those involving bankrupt medical facilities), DHS revisited the sites, and found that the allegedly missing sources were still stored at the former licensed locations of use. In one case, the facility had not been reoccupied, and the facility remained secure from the time the licensee left until DHS revisited the site. DHS took possession of those sources at the time of the visit, and is storing them for eventual disposal as radioactive waste. In another case, a new medical licensee had taken possession of the property since the last visit by DHS, and their license authorized them to possess the type, form and amount of materials left at the site. Those materials were left on site in possession of the new licensee.

With respect to the two gauge licensees referenced in your letter, one is licensed only for lead analyzer containing radioactive material that is not regulated pursuant to the Atomic Energy Act (i.e., accelerator-produced material), and the sole gauge in his possession during the last inspection would have already decayed to negligible levels. DHS made additional efforts to locate this licensee. This was a sole proprietorship, and the owner's name is one that is extremely common in California and all efforts to find this gentleman have been unsuccessful. DHS plans to administratively terminate this license.

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Internet Address: www.dhs.ca.gov

DHS is still actively engaged in finding the final licensee. DHS has recently received additional information regarding this licensee, and will be attempting to make contact and identify the current location of the licensee's gauge. It should be noted, that this licensee was only authorized to possess one soil gauge. While DHS appreciates the seriousness of accounting for this radioactive material, in light of the dozens of lost, abandoned, or stolen gauges every year, the loss of this one gauge does not appear to be a significant impact on the overall safety and security of radioactive material. Nevertheless, DHS intends to make a diligent effort to locate this licensee and the gauge.

In addition to the actions taken to address the four licensees referenced in your letter, DHS examined these events to determine whether there was a likelihood that similar events could occur in the future. Two issues contributing to these events were identified: 1) insufficient communication between the Inspection, Compliance and Enforcement (ICE) staff and the Licensing staff, and 2) inordinate delays in the responding to termination requests by two of the licensees involved in these events. In order to address these issues, DHS has instructed the ICE and Licensing staffs to coordinate on a review of all pending license termination requests, and to evaluate whether additional site visits may be necessary to ensure that licensees with pending termination requests have either properly disposed of their remaining radioactive materials or are maintaining active control over the materials pending a response from DHS regarding their proposed disposition of the materials. This evaluation is still on going, and the results can be provided to you upon its completion.

DHS hopes this information is responsive to your concerns. If you have further questions in this regard, please contact me at 916-440-7899.

Sincerely,

Edgar D. Bailey, C.H.P., Chief
California Department of Health Services
Radiologic Health Branch