July 11, 2006

Kevin Reilly, DVM, MPVM
Deputy Director
Prevention Services
California Department of Health Services
P. O. Box 997413, MS-7600
Sacramento, CA 95899-7413

Dear Dr. Reilly:

On June 15, 2006, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the California Agreement State Program. The MRB found the California program adequate, but needs improvement, and not compatible with the U.S. Nuclear Regulatory Commission's (NRC) program. The MRB directed that the period of heightened oversight of the California Agreement State program be continued.

As noted during the IMPEP review and discussed during the MRB meeting, the Radiologic Health Branch (the Branch) has implemented many program improvements. These improvements included: promulgating a new fee system, hiring of technical staff, addressing weaknesses identified in the incident and allegations programs, and adopting overdue regulations. These actions demonstrate a high level of management support for the Agreement State program by the Department of Health and Human Services and a continued commitment to operating a fully satisfactory program in the future.

The MRB agreed with the review team that additional time and actions are necessary before the Branch can reach and sustain a level of satisfactory performance. The MRB also agrees that the positive effect of the improvements mentioned above has not yet been fully realized within the Branch due to the short time between the new initiatives and the on-site review.

As you know, 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 noted that the Branch has completed six of ten items identified on the performance improvement plan since the special review of the program improvement plan conducted in May 2005. We request that you prepare and submit a revised program improvement plan addressing the outstanding items from the previous plan as part of your response to the remaining open recommendations in Section 3 of the enclosed final report. I ask that you have your staff continue dialogue with Janet Schlueter, Director, Office of State and Tribal Programs, on the required elements of the revised plan to ensure that milestones for resolving the NRC's recommendations are clearly identified. The revised plan should be submitted within 30 days of receipt this letter. Upon

review of the revised program improvement plan, the staff will schedule the next conference call. The conference call should be scheduled and conducted no later than September 30, 2006. Based on the results of the follow-up IMPEP review, a full IMPEP review will be cheduled during the period March 2007 - September 2007.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge the continued support for the Agreement State program and the excellence in program administration demonstrated by your staff, as reflected in the team's findings. I look forward to our agencies continuing to work cooperatively in the future.

If you have any questions regarding this correspondence, please contact Janet R. Schlueter, at (301) 415-3340.

Sincerely,

/RA/

Martin J. Virgilio
Deputy Executive Director for Materials, Research,
State and Compliance Programs
Office of the Executive Director for Operations

Enclosure:
As stated

cc: Richard Rodrigus, Assistant Deputy Director, Prevention Services
Larry Barrett, DVM, Chief, Division of Food, Drug and Radiation Safety
Gary Butner, Acting Chief, Radiologic Health Branch
James D. Boyd, State Liaison Officer

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

FOLLOW-UP REVIEW OF CALIFORNIA AGREEMENT STATE PROGRAM

March 27-30, 2006

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the follow-up review of the California Agreement State program, conducted March 27-30, 2006. This follow-up review was directed by the Management Review Board (MRB) based on the results of the April 26-30, 2004, Integrated Materials Performance Evaluation Program (IMPEP) review and the May 24-27, 2005, special review of the implementation of the California Program Improvement Plan (the Plan).

The follow-up review was conducted by a review team consisting of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Agreement State of North Carolina. Review team members are identified in Appendix A. The follow-up review was conducted in accordance with the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the follow-up review, which covered the period of April 30, 2004 to March 30, 2006, were discussed with California management on the last day of the review.

A draft of this report was issued to California for factual comment on April 27, 2006. California responded to the findings and conclusions of the review by e-mail dated May 30, 2006, from Mr. Gary Butner, Acting Chief, Radiologic Health Branch (the Branch). The Management Review Board (MRB) met on June 15, 2006, to consider the proposed final report. The MRB found the California Agreement State Program adequate, but needs improvement, and not compatible with NRC's program. The MRB directed that the period of heightened oversight of the California Agreement State Program be continued.

The California Agreement State program is administered by the Radiologic Health Branch (the Branch). The Branch is located in the Division of Food, Drug, and Radiation Safety (the Division), which is part of Preventive Services within the Department of Health Services (the Department). Organization charts for the Governor's office, the Department, the Division and the Branch are included as Appendix B. At the time of the review, the California program regulated approximately 2,029 specific licenses authorizing radioactive materials. The review focused on the materials 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 2004, the MRB found the California Agreement State program adequate, but needs improvement, and not compatible with NRC's program. Because of the significance of the findings, the MRB directed that the State be placed on heightened oversight. The MRB directed that a follow-up review take place approximately one year after the 2004 MRB meeting.

The Branch submitted its first Plan as part of the heightened oversight process in June 2004. NRC staff had many concerns with the Plan including, lack of milestones, incorrect data and complicated format. From June 2004 to April 2005, NRC staff held bimonthly teleconferences with the Branch to try to achieve resolution on the effectiveness of the Plan and evaluate if the Branch was making progress towards completing the corrective actions. A listing of correspondence and summaries from the bimonthly calls is included as Appendix C.

In April 2005, NRC management determined that the Branch showed little progress in completing actions identified in their Plan and a special review team was dispatched to California. A special on-site review of the Plan took place May 24-27, 2005. The special review team concluded, and the MRB agreed, that the Plan was not being utilized as an effective

management tool, and that the responsibility for evaluating the effectiveness of the Plan appeared to be at the staff level, without direct management oversight. State management indicated during the exit meeting that the Plan would be revised with management involvement. In addition, State management indicated that future updates would be sent directly from the Division Chief to the NRC to ensure that senior management reviews and approves the Plan prior to submission to the NRC and also to evaluate progress on the corrective actions. The NRC received a revised Plan from California on July 14, 2005. NRC staff concluded that the revised Plan was an improvement from previous versions of the Plan and met the requirements of the heightened oversight process.

During the 2005 MRB meeting, the MRB directed that the period of heightened oversight be continued to monitor the Program's progress in completing the actions identified in the revised Plan and the follow-up IMPEP review be scheduled for March of 2006.

The follow-up review focused on the State's performance in regard to the common performance indicators, Technical Staffing and Training and Technical Quality of Incident and Allegation Activities, and the non-common performance indicator, Compatibility Requirements. The follow-up review also included evaluation of the actions taken by California to address the recommendations made during the 2004 IMPEP review. Other aspects of the program not fully evaluated as part of the follow-up review, were discussed at a periodic meeting held in conjunction with the review. The periodic meeting summary is included as Appendix D.

In preparation for the follow-up review, a questionnaire addressing the common performance indicator, Technical Staffing and Training, was sent to the Branch on February 2, 2006. The Branch provided a response to the questionnaire on March 14, 2006. A copy of the questionnaire response can be found on NRC's Agency-wide Document Access and Management System (ADAMS) using the Accession Number ML061160449.

The review team's general approach for conduct of this follow-up review consisted of: (1) examination of California's response to the questionnaire; (2) review of the heightened oversight information including status reports; (3) review of applicable California statutes and regulations; (4) analysis of information from the Branch's incident and allegation tracking system; and, (5) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information gathered against the IMPEP performance criteria for the two common and one non-common performance indicators and made a preliminary assessment of the Agreement State program's performance.

Section 2 below discusses the results of the follow-up review of the California program for the two common performance indicators. Section 3 below discusses the results of the follow-up review of the California program for the one non-common performance indicator. Section 4 summarizes the follow-up review team's findings and open recommendations.

2.0 COMMON PERFORMANCE INDICATORS

The follow-up review addressed two of the five common performance indicators used in reviewing both NRC Regional and Agreement State programs, Technical Staffing and Training and Technical Quality of Incident and Allegation Activities.

2.1 Technical Staffing and Training

During the follow-up review, the review team evaluated actions taken by the State in response to the finding of satisfactory, but needs improvement made during the 2004 IMPEP review, as well as the status of the staffing and training of the Branch's program.

Issues central to the evaluation of the staffing and training 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 response relative to this indicator, interviewed Branch management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

The review team's evaluation of the State's response to Recommendation 1, from the 2004 IMPEP review, is presented below.

Recommendation 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 of the 2004 IMPEP Report)

Current Status:

At the time of the follow-up review, the fee package that the Branch had been pursuing for many years was approved as an emergency rule in October 2005. Division management indicated that with the fee package approved, the Branch's annual budget increased from 13 to 21 million dollars. The increase in the budget is crucial for the Branch's staffing initiatives, as well as overall support of the program.

The Branch is composed from four sections: the Financial Operations and Analysis Section; the Registration, Certification, Mammography and Standards Section; the Radioactive Materials Licensing Section; and the Inspection, Compliance, and Enforcement (ICE) Section. All Sections report to the Branch Chief. Due to a recent retirement of the Branch Chief, the Sections report to an acting Branch Chief. The Branch has three Section Chiefs and one acting Section Chief. A recent realignment in the ICE Section separated X-ray inspection from the materials inspection program. The change creates a Section specifically for radioactive materials inspection and a new Section for machine inspection. The realignment allows for streamlining management and simplifying oversight of the radioactive materials inspection section.

The ICE Section is operated out of the Sacramento office and two regional offices, identified as the Northern and Southern California program offices. Each of the regional offices has a Senior Health Physicist. Seven Associate Health Physicists are spread amongst the two offices. Two Junior Health Physicists were added to the Southern office. The Northern office has one Associate Health Physicist vacancy and the Southern office has two Associate Health Physicist vacancies. Two offers have been made to fill two of the vacancies. 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. At the time of the review, the total number of health physicist positions in the ICE Section was 13, five less than in 2004.

In May 2005, ICE reassigned inspectors from the Berkeley (now part of the Northern office) and Sacramento offices to perform overdue inspections in the Granada Hills office (now part of the Southern office). The Branch also reassigned licensing reviewers with inspector qualifications to assist in addressing the inspection backlog and open event reports in the Los Angeles County office. This was accomplished with overtime.

The Regulations Unit reports directly to the Branch Chief and is staffed by a Health Program Manager, a Senior Health Physicist, two Associate Health Physicists, and one Analyst. The second Associate Health Physicist position was recently added to assist in drafting and promulgating the overdue regulations.

A program strength noted by the review team is the Financial Operations and Analysis Section that serves in a support role for the Branch. This Section's responsibilities include database support, special projects support, financial operations, and other program support functions.

The review team recognized significant staffing improvements to the Branch since the previous review. The review team believes that the staffing, reorganizing and realigning of the Branch should enhance management oversight. The aforementioned reassignments may affect other programs (e.g., the licensing program which has three vacancies and an acting supervisor). The current level of staffing may not be able to sustain the inspection timeliness, nor be able to absorb any future increased demands on the program. Although significant staffing improvements were noted during this review, the review team believes that additional time is required for the Branch to exhibit stability in staffing and to reach and sustain a level of satisfactory performance for this indicator. The review team recommends that Recommendation 1 remain open.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that California's performance with respect to the indicator, Technical Staffing and Training, continues to be satisfactory, but needs improvement.

2.2 Technical Quality of Incident and Allegation Activities

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

The review team interviewed Branch management 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 eight incidents selected for review included the following types: lost/stolen material, medical events and leaking sources. The review team found the quality of the incident and allegation activities to be improved since the 2004 review.

The review team's evaluation of the State's response to Recommendation 5, 6 and 7 from the 2004 IMPEP review, is presented below.

Recommendation 5:

The review team recommends that the Branch, in coordination with INEEL, complete and close all reportable incidents in NMED. (Section 3.5 of the 2004 IMPEP report)

Current Status:

When the Branch is notified of an incident or allegation, a form titled, "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. Information about the event is then reported via e-mail to the NRC's NMED Contractor, Idaho National Laboratories (INL) (formerly Idaho National Engineering and Environmental Laboratories (INEEL). The Branch does not currently utilize the NMED software program. In order to close an investigation, the responsible staff member must include a printout from the NMED website showing the event record being complete and a "Materials Investigation Closing Memo" is completed and placed in the investigation file. A "narrative report" that details all aspects of the investigation must also accompany the file. The investigation file is then reviewed by a senior health physicist for review and approval. Then the file is forwarded to the Branch's NMED Coordinator and the closing information is transmitted to INL.

The ICE Section has written procedures for handling investigations of incidents, which were revised in August 2005 following the 2004 IMPEP. The procedure has general guidance on use of the tracking database and generation of the appropriate forms and reports; how to handle immediate, 24 hour, and 30 day notifications; and points of contact for each. The Branch also has a procedure revised in September 2005, which deals with materials events reporting to NMED.

During the review period, the Branch changed their inspection frequencies to more closely match the NRC inspection frequencies. This created a "window of opportunity" for work to be completed on the follow-up of open and incomplete incidents. The Branch suspended all inspection activities during March 2006 and was able to close a majority of the open incidents during this time, some of which were open since 2004. Of the 172 open incidents identified in the 2004 review, eight remain open. For those incidents which have been investigated since May 1, 2004, five incidents that are open, with four being open greater than 90 days.

The Branch has made significant improvements in response to Recommendation 5 since the previous review. The review team concluded that the Branch successfully addressed the backlog of work for the open and incomplete incidents as appropriate and established a program to prevent recurrence through the revision of procedures. While the review team noted significant improvements, the improvements have not been in place long enough to truly evaluate their effectiveness. The review team recommends that Recommendation 5 remain open.

Recommendation 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 of the 2004 IMPEP report)

Current Status:

The review team queried the incident information reported to the NMED system for the review period and identified 133 contained in NMED. Of the 133, two were not complete and additional information needs to be provided to INL. In addition, 13 of the 133 reportable incidents were not closed in NMED. The Branch has made significant progress in reducing both the number of incidents requiring additional information provided to NMED and in the number of open cases in NMED.

The team reviewed records maintained by the Branch which note the date that reportable events are submitted to NMED against the NMED database. Of the 133 incidents which were reported to INL during the review period, only five were not reported within 30 days of the Branch being notified of the event. This is a significant reduction in the number of incidents which were not reported to NMED within the required time. The review team concluded that the Branch is submitting reportable events to NMED in accordance with the Office of State and Tribal Programs (STP) Procedure SA -300, *Reporting Material Events*, which includes the Handbook on Nuclear Material Event Reporting in the Agreement States. The review team recommends that Recommendation 6 be closed.

Recommendation 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 of the 2004 IMPEP report)

Current Status:

As noted above, the Branch has established and implemented a system to track incident and allegation investigations to ensure timeliness, proper documentation, appropriate follow-up and closure. The Division Chief receives periodic reports on the status of the investigations.

During the review period, six allegations were referred to the Branch by the NRC. The team reviewed four of these allegations. Subject matters for the four allegations referred to the State by the NRC included improper distribution of exempt material, illegal possession of radioactive material, and improper following of procedures.

The review team's evaluation of the ICE Section's allegation files indicated that appropriate action was taken in response to the concerns, and prompt action taken in two of the cases. An internal tracking problem contributed to the delay in response to two of the cases. An allegation tracking system for allegations from NRC was implemented by the Branch during the review to

address the internal tracking problem. The Branch committed to properly address these allegations and coordinate with the NRC as appropriate.

The review team is concerned about the Branch's ability to sustain the performance in tracking incident and allegation investigations to ensure timeliness, proper documentation, appropriate follow up and closure without the redirection of staff. The review team believes that the Branch needs additional time to demonstrate satisfactory performance in addressing this recommendation. The review team recommends that Recommendation 7 remain open.

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

3.0 NON-COMMON PERFORMANCE INDICATORS

The follow-up review addressed one of the non-common performance indicators used in reviewing NRC Regional and Agreement State programs, "Compatibility Requirements."

3.1 Compatibility Requirements

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 and accelerator-produced radioactive materials.

The review team's evaluation of the State's response to Recommendation 8, from the 2004 IMPEP review, is presented below.

Recommendation 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 4.1.2 of the 2004 IMPEP report).

Current Status:

The review team 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 State Regulation Status (SRS) sheet as maintained by STP.

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, 10 CFR Part 20 radiation protection regulations, and Part 36 Radiation Safety Requirements for Irradiators.

Since the last IMPEP review, the State has adopted two amendments. The State passed Deliberate Misconduct regulations and adopted a Part 36 equivalent by reference. In addition, the Branch implemented, through license conditions, the increased controls for risk-significant radioactive sources (NRC Order EA 05-090). There are currently 18 regulatory amendments that the State is overdue in adopting.

Since the April 2004 IMPEP review, there has been significant effort in developing and submitting the rule packages into the rulemaking process. Six of the overdue amendments, at least in part, have been reviewed by the NRC as proposed regulations. These include Part 34 Industrial Radiography regulations, Part 20 Skin Dose and Respiratory Protection controls, Part 39 Well Logging controls, and Part 30 Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea regulations. Part 71 Transportation, Part 31 Generally Licensed Device, and Part 35 Medical regulation packages are currently being drafted by the Branch.

The review team reviewed different license files for verification of Part 36 Irradiator, Part 32.52 GL Device Manufacturer and Distributor requirements, and Part 34 "Two-Person Rule" incorporation by license condition. The review team found proper license condition incorporation in each case.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they are effective. The following 18 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.

- “Termination or Transfer of Licensed Activities: Recordkeeping Requirements,” 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective on June 17, 1999. The Branch adopted equivalent regulations to the Part 20 requirements of this amendment by reference to 10 CFR Part 20 as printed on January 1, 1999.

- "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.

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendment (62 FR 39057) that became effective August 20, 1997. The 10 CFR Part 20 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 Branch’s currently terminating licenses on a case-by-case basis.

- "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.

- "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.

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendment (65 FR 79162) that became effective on February 16, 2001.

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

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:

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

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697) that became effective on October 1, 2004.

- "Security Requirements for Portable Gauges Containing Byproduct Material," 10 CFR Part 30 amendment (70 CFR 2001) that became effective on July 11, 2005.

- "Medical Use of Byproduct Materials - Recognition of Specialty Boards - Part 35," 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926) that became effective on April 29, 2005.

Due to the number of overdue amendments, the review team recommends that Recommendation 8 remain open.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that California's performance with respect to the indicator, Compatibility Requirements, continues to be unsatisfactory.

4.0 SUMMARY

The follow-up review team found California's performance to be satisfactory, but needs improvement for the indicators, Technical Staffing and Training and Technical Quality of Incident and Allegation Program, and unsatisfactory for the indicator, Compatibility Requirements. The review team noted that the program has made significant progress in management oversight of the Branch. However, the review team believes that additional time and actions are necessary before the Branch can reach and sustain a level of satisfactory performance. Accordingly, the review team recommended and the MRB agreed that the California Agreement State Program continues to be adequate, but needs improvement, and not compatible with NRC's program. The review team recommended and the MRB agreed that the period of heightened oversight continue in order to assess the progress of the State in implementing corrective actions in a revised Plan addressing open recommendations from this review. Bimonthly status reports and bi-monthly conference calls to discuss progress on the State's revised Plan should also continue. Based on the results of the review, the review team recommends that the next full IMPEP review take place in approximately 12-18 months.

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 2.1)

2. The review team recommends that the Branch, in coordination with INL, complete and close all reportable incidents in NMED. (Section 2.2)

3. 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 2.2)

4. 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 3.1)

LIST OF APPENDICES AND ATTACHMENT

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Kathleen Schneider, STP	Team Leader Technical Staffing and Training Periodic Meeting
Linda McLean, RIV	Technical Staffing and Training Periodic Meeting
William Rautzen, STP	Compatibility Requirements
Marion Eaddy, North Carolina	Technical Quality of Incident and Allegation Activities

APPENDIX B

CALIFORNIA
ORGANIZATIONAL CHARTS

ADAMS ACCESSION NO.: ML061160449

GOVERNOR ARNOLD SCHWARZENEGGER

S. KIMBERLY BELSHÉ, SECRETARY
HEALTH AND HUMAN SERVICES AGENCY

SANDRA SHEWRY, DIRECTOR
DEPARTMENT OF HEALTH SERVICES

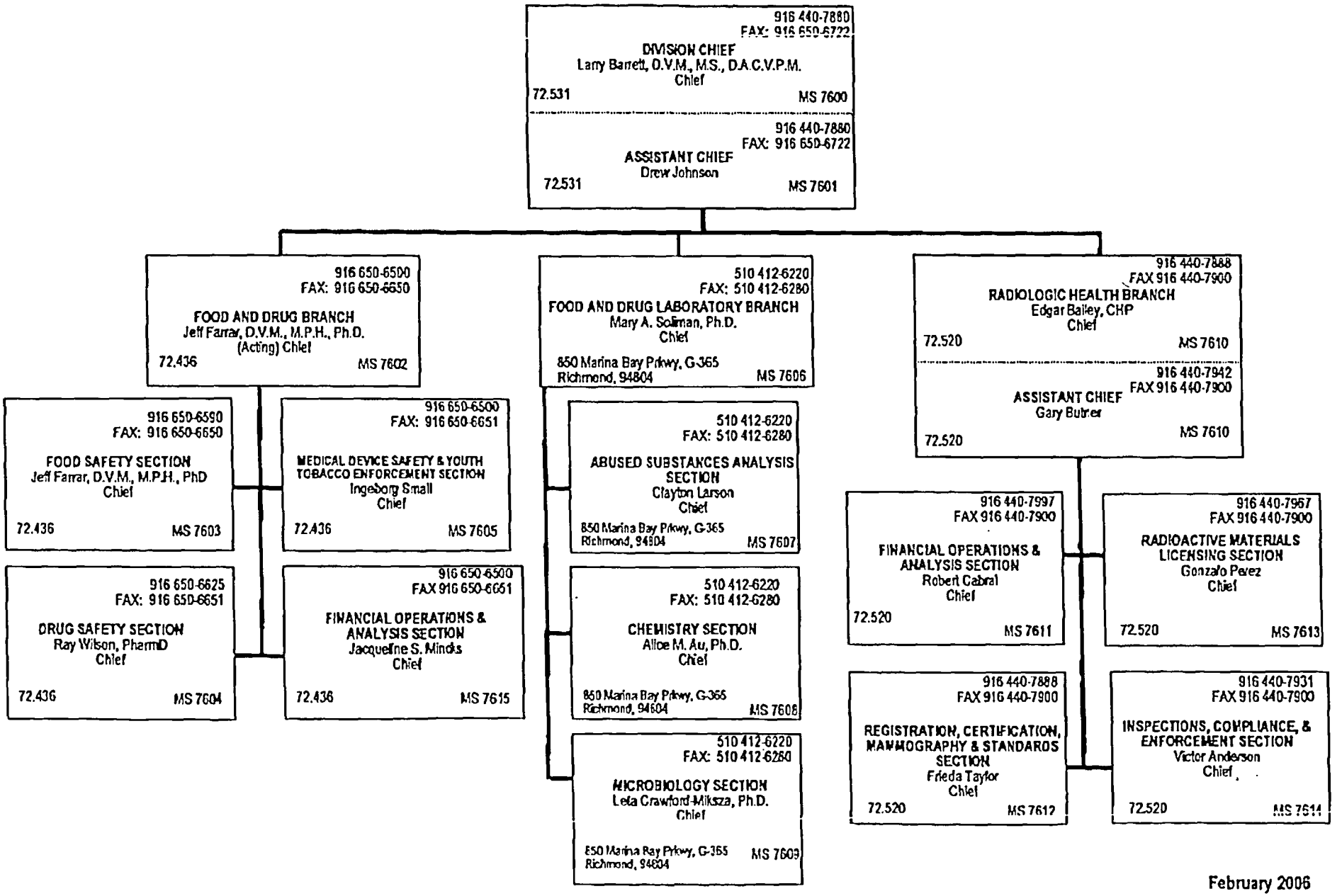
MARK HORTON, M.D., M.S.P.H., CHIEF DEPUTY DIRECTOR
DEPARTMENT OF HEALTH SERVICES

KEVIN REILLY, D.V.M., M.P.V.M., DEPUTY DIRECTOR,
PREVENTION SERVICES

LARRY BARRETT, D.V.M., M.S., CHIEF
DIVISION OF FOOD, DRUG AND RADIATION SAFETY

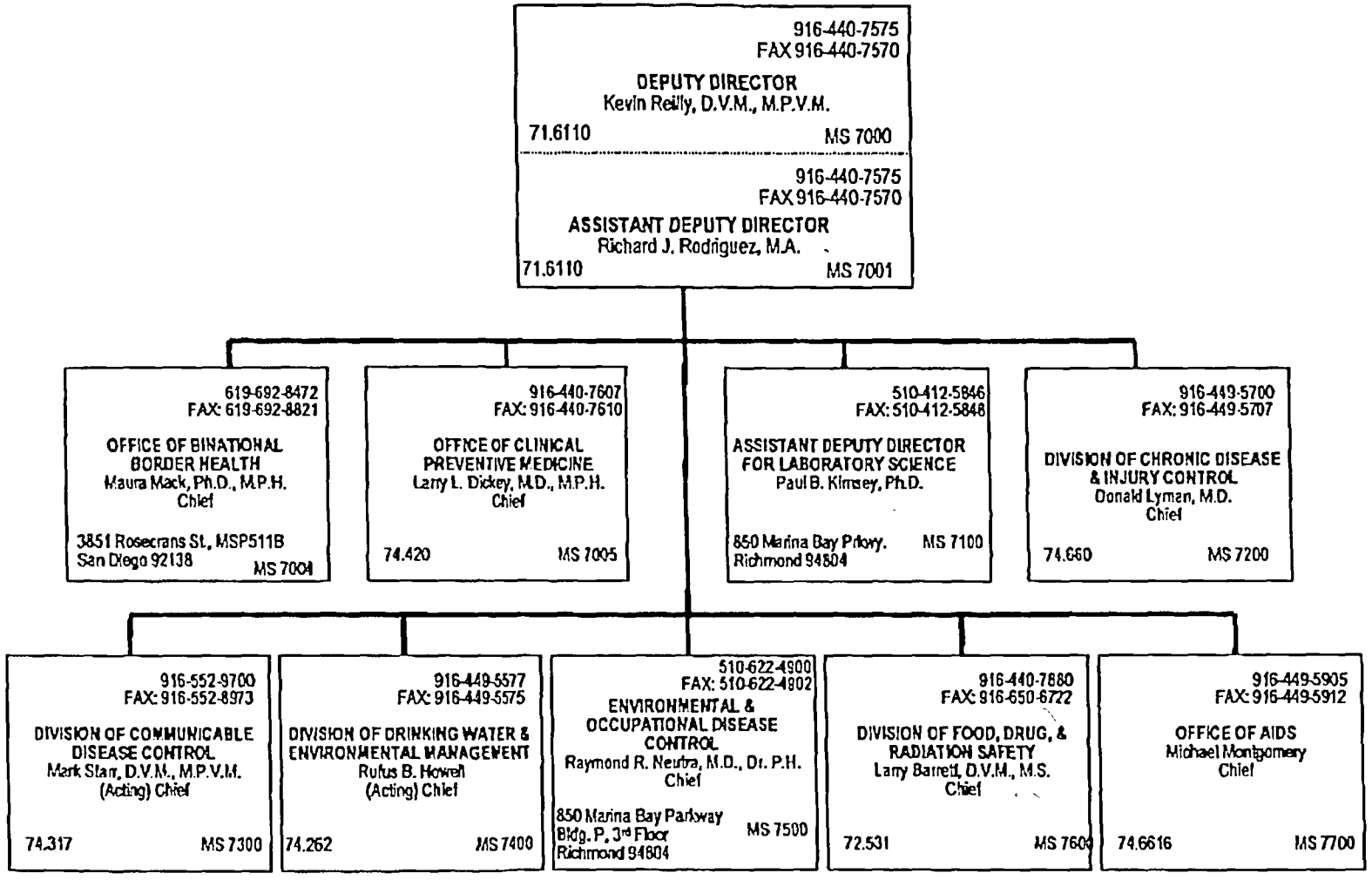
EDGAR D. BAILEY, C.H.P., PE, CHIEF
RADIOLOGIC HEALTH BRANCH

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



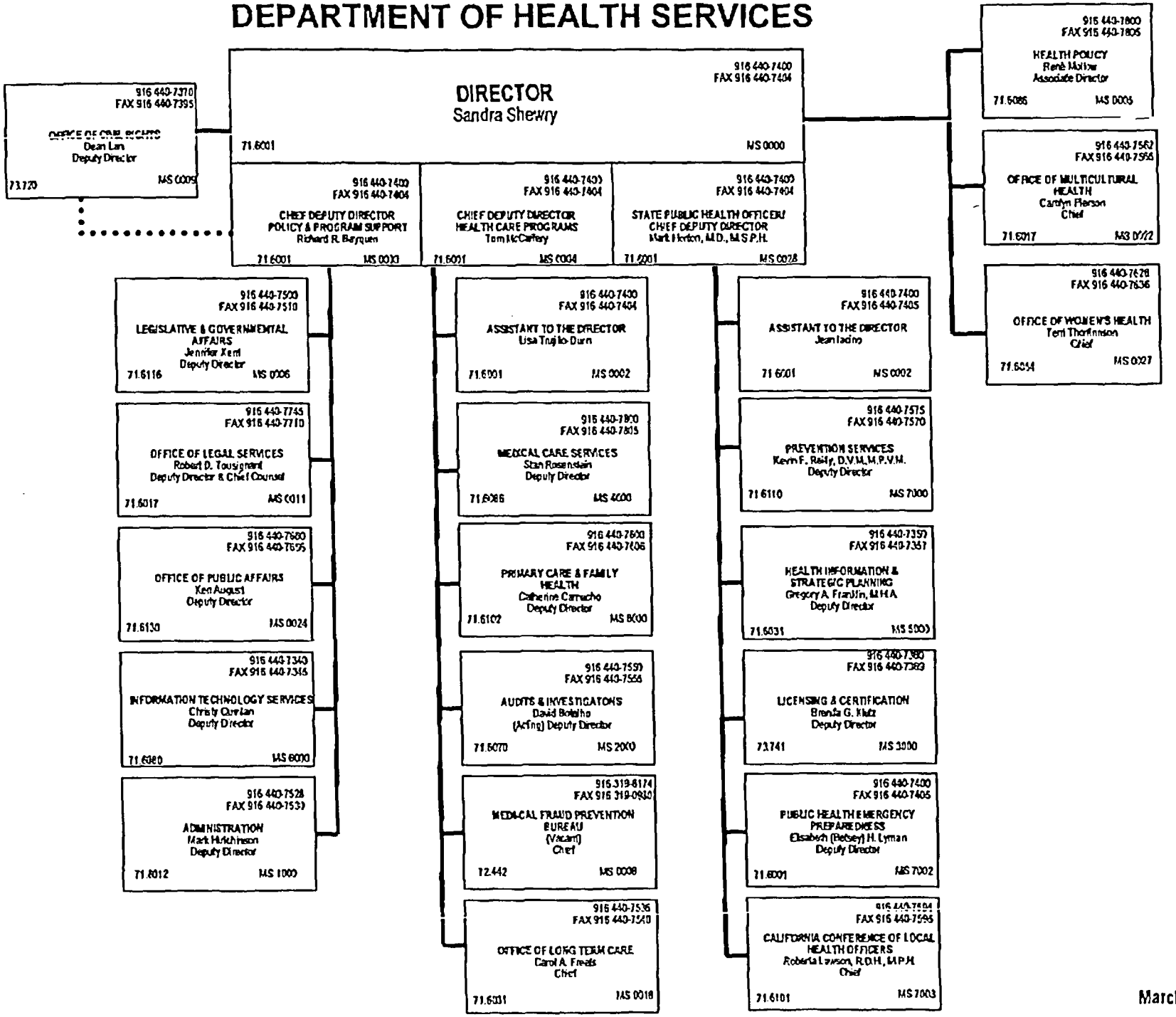
February 2006

CALIFORNIA DEPARTMENT OF HEALTH SERVICES
PREVENTION SERVICES



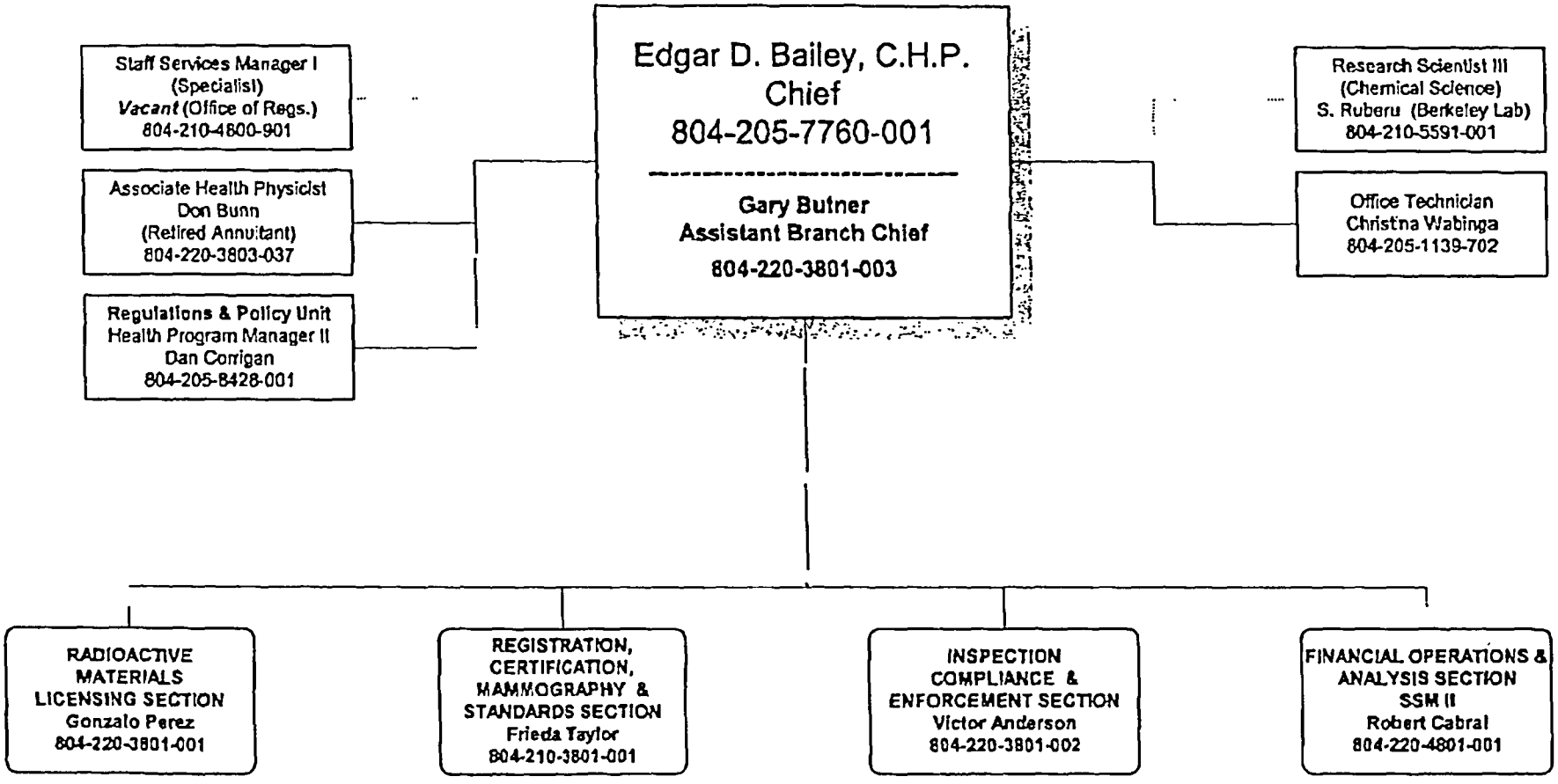
February 2006

CALIFORNIA
DEPARTMENT OF HEALTH SERVICES



March 2006

Radiologic Health Branch
Division of Food, Drug, and Radiation Safety



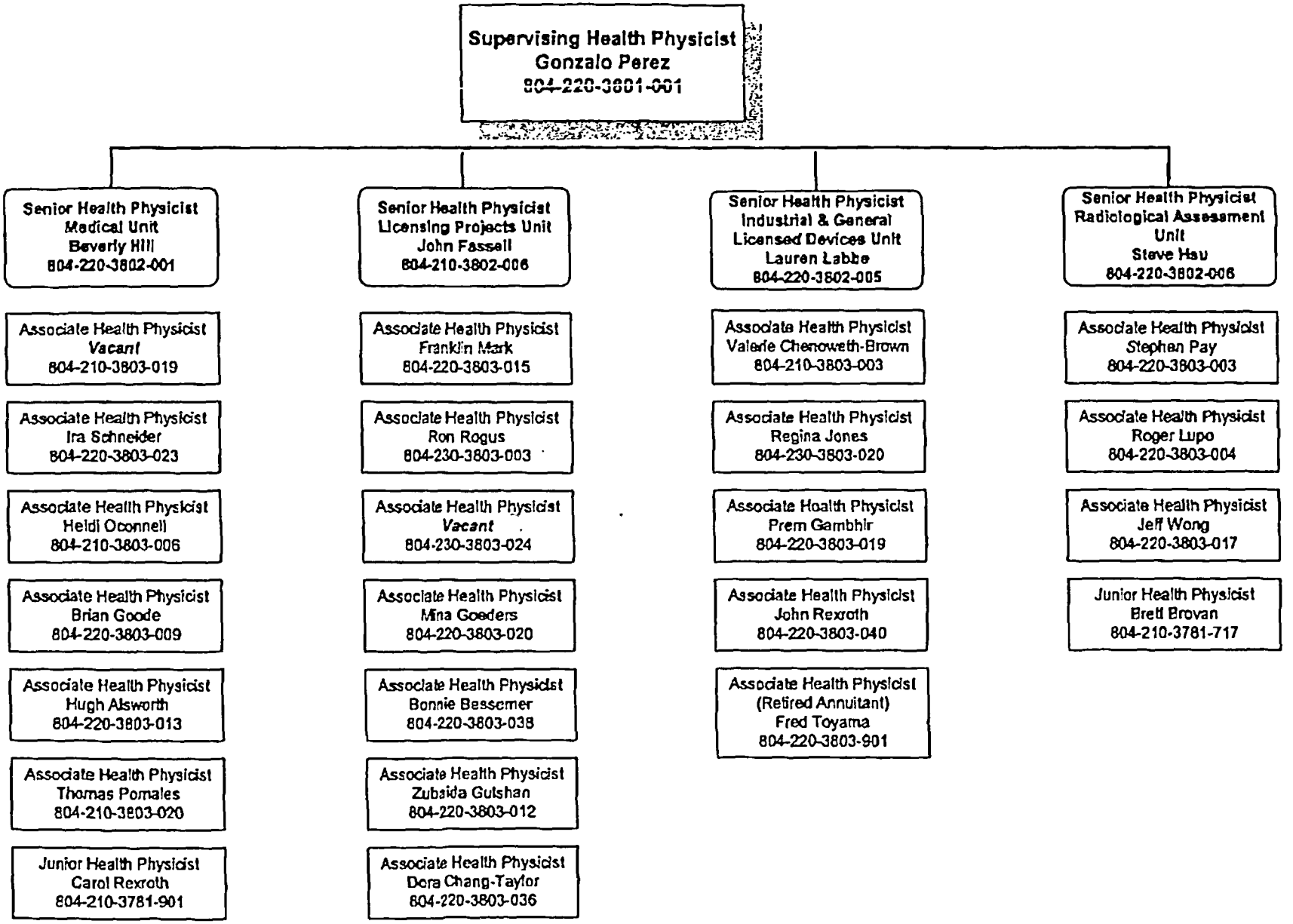
Approved:

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

Org 03-01-06

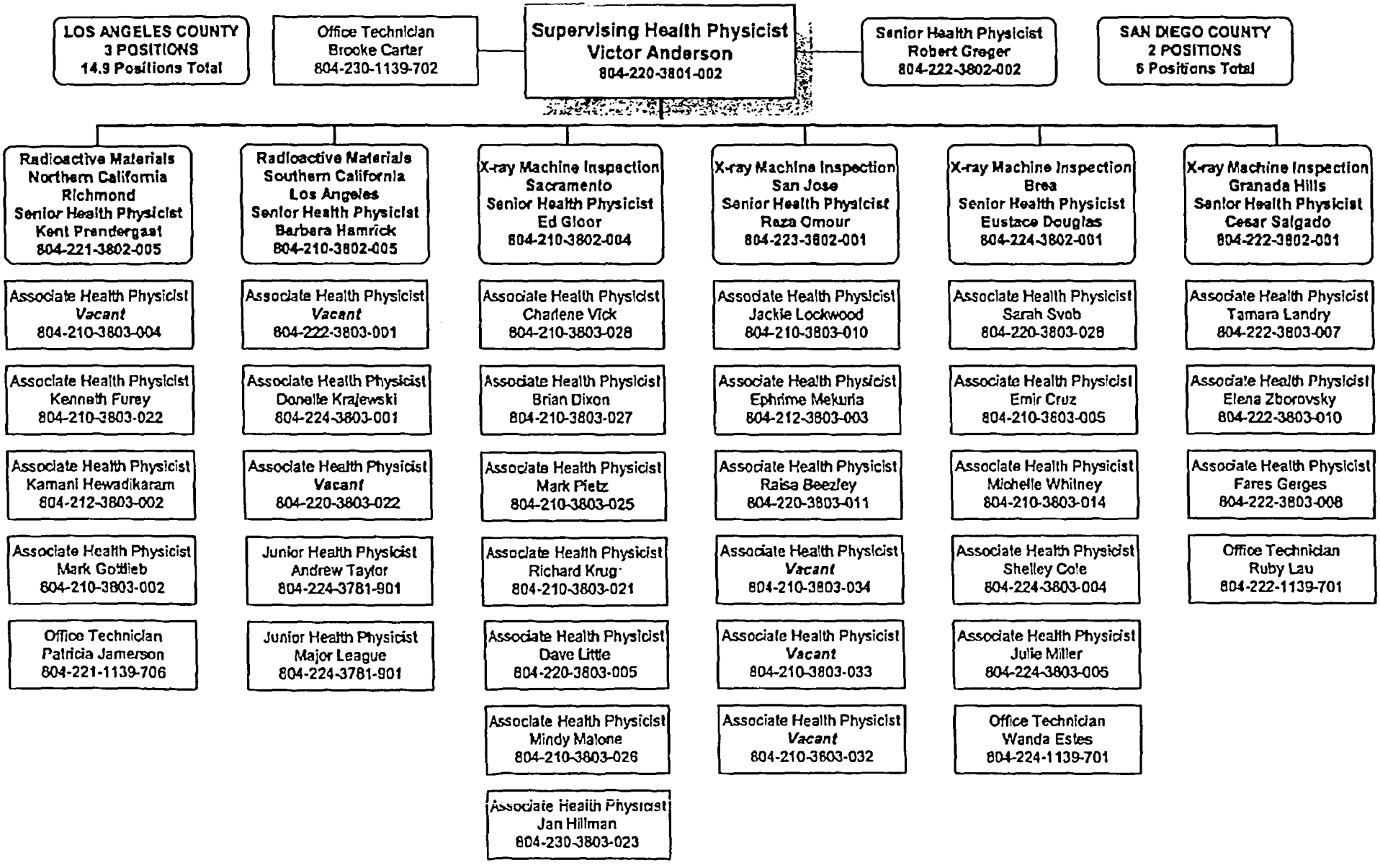
Larry Barrett, D.V.M., M.S., DACVPM Chief, Food, Drug & Radiation Safety

Radioactive Materials Licensing Section



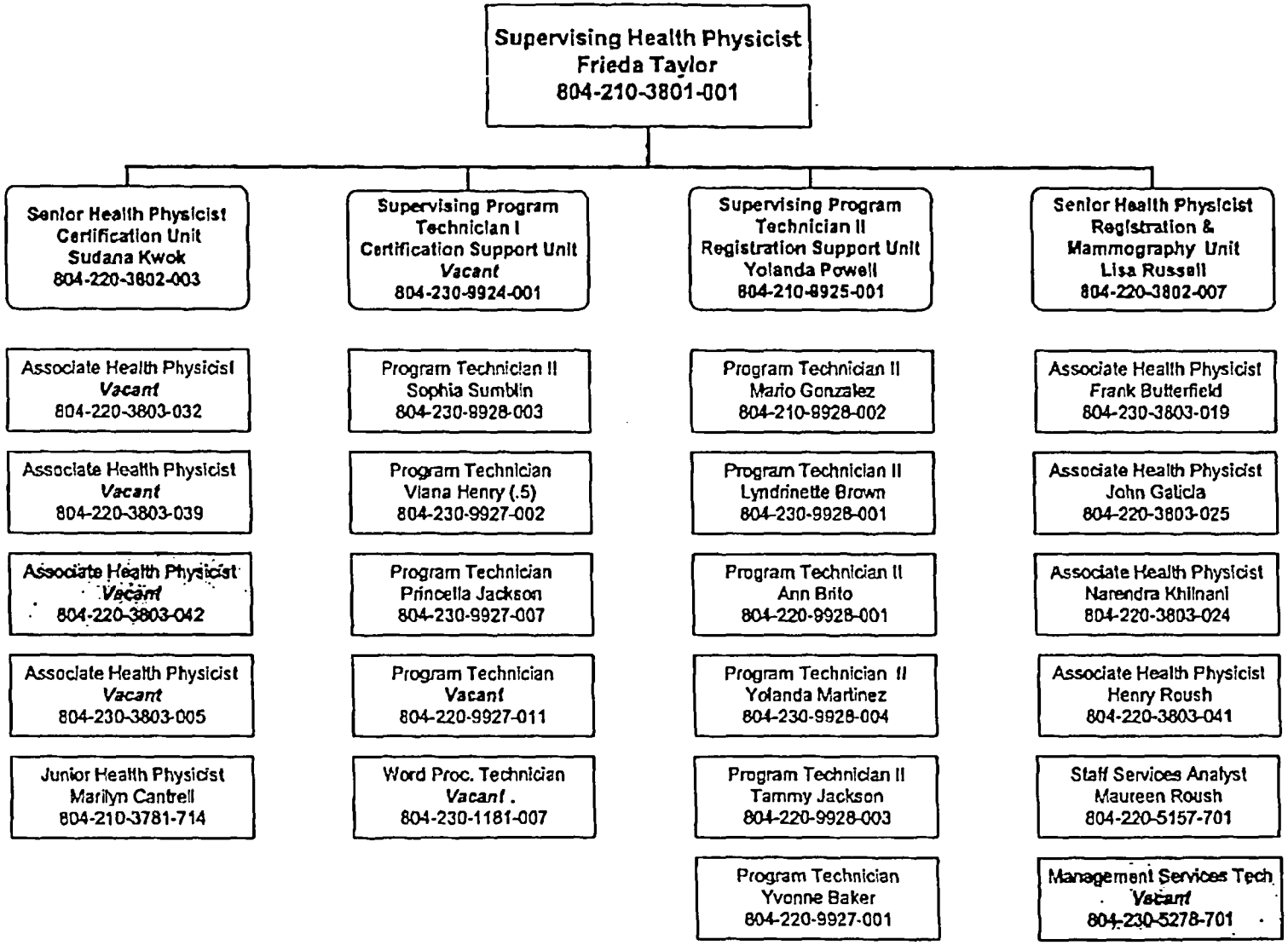
Org 03-01-06

Inspection, Compliance and Enforcement Section



ORG 03-01-06

Registration, Certification, Mammography and Standards Section



Org 03-01-06

Regulations Unit

Health Program Manager II
Dan Corrigan
804-205-8428-001

Senior Health Physicist
Phillip Scott
804-220-3802-004

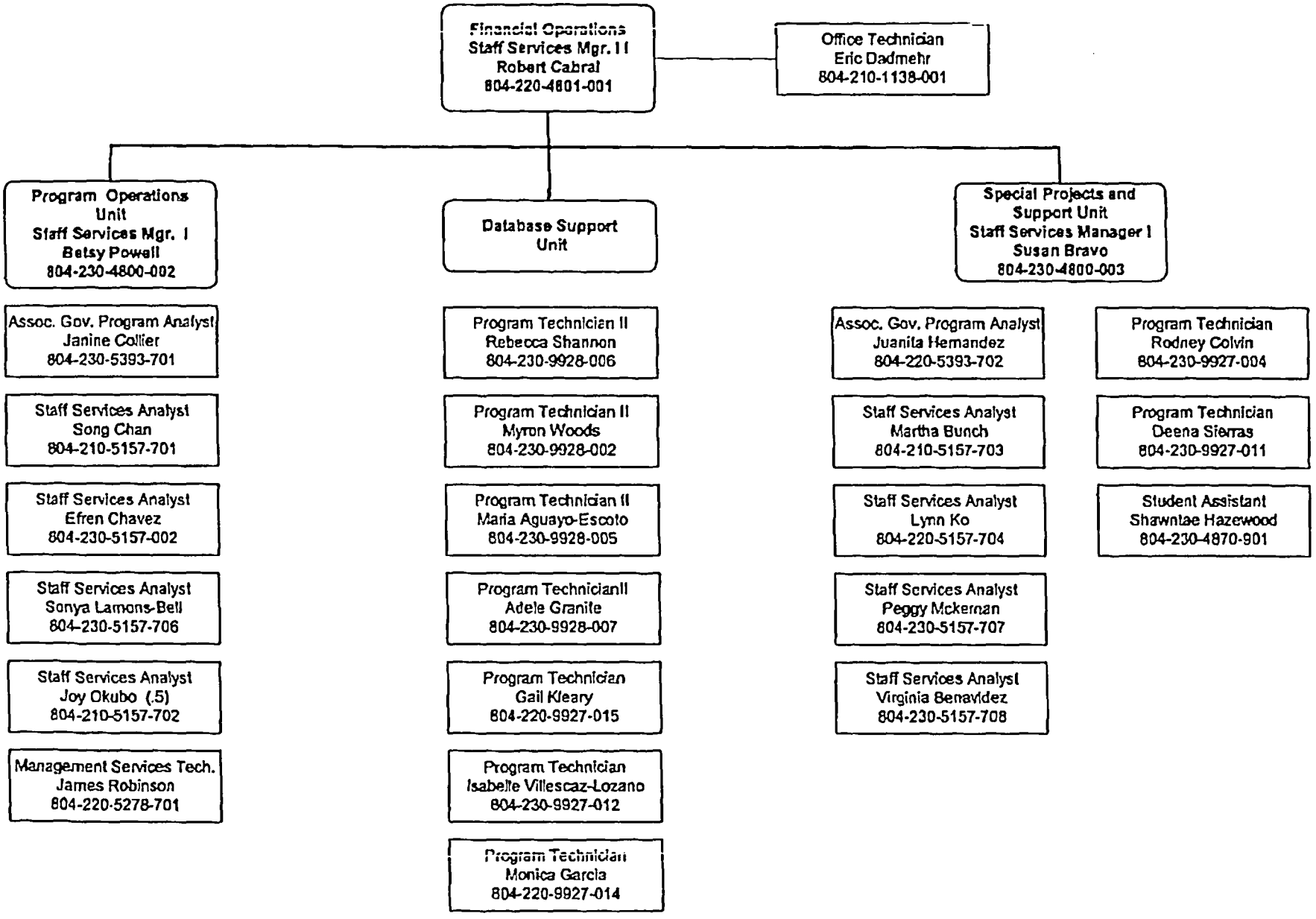
Associate Health Physicist
Leo Spencer
804-230-3803-004

Associate Health Physicist
Jennifer Granger
804-220-3803-901

Assoc. Gov. Program Analyst
Judy Hardy
804-230-5393-703

Org 03-01-06

Financial Operations and Analysis Section



APPENDIX C

HEIGHTENED OVERSIGHT PROGRAM CORRESPONDENCE

Minutes of Bimonthly Conference Calls:

1. November 4, 2004 Minutes (ML043450350)
2. December 8, 2005 Minutes (ML060270594)
3. March 24, 2005 Minutes (ML052910552)
4. August 2, 2005 Minutes (ML052920157)
5. February 9, 2006 Minutes (ML060600547)

Letters from/to California:

1. August 8, 2004 Letter to Richard J. Jackson from M. J. Virgilio, California Final IMPEP Report (ML042170340)
2. September 24, 2004 Letter to M. J. Virgilio, Response to the California IMPEP Final Report (ML043280265)
3. October 20, 2004 Letter to Richard J. Jackson, Response to September 24, 2004 letter and e-mail regarding California Final IMPEP Report (ML042930322)
4. December 6, 2004 Letter to M. J. Virgilio from Richard. J. Jackson, Response to Integrated Materials Performance Evaluation Program Review of California Agreement State Program (ML043480145)
5. May 19, 2005 Letter to E. Bailey from L. McLean, Scheduling a special review meeting to be held May 23-26, 2005 (ML051390204)
6. June 30, 2005 Letter to Larry Barrett from L. McLean, Results of the California Special review meeting (ML051820115)
7. July 29, 2005 Letter to Larry Barrett from Paul Lohaus, Comments on the July 7, 2005 California Program Improvement Plan (ML052100251)
8. September 9, 2005 Letter to Larry Barrett from M. Virgilio, Results of Special Review of California's Program Improvement Plan (ML052510524)

APPENDIX D

PERIODIC MEETING SUMMARY

A periodic meeting was held with the Acting Branch Chief by Kathleen Schneider, Team Leader, and Linda McLean, Regional State Agreements Officer (RSAO), during the follow-up review pursuant to the Office of State and Tribal Programs (STP) Procedure SA-116, "Periodic Meetings with Agreement States Between IMPEP Reviews." Those topics normally documented during the periodic meeting that were reviewed and documented as part of the follow-up review will not be discussed in this Appendix. The following topics were discussed.

1. Status of Recommendations from 2004 Report

See Sections 2.1 and 3.1 for details on Recommendations 1, 5, 6, 7 and 8. It is practice to recommend that items and recommendations that were not reviewed as part of the specific performance indicators during the follow-up review be closed at the next IMPEP review. However, the review team recommends that the following five recommendation be closed at this time based on the file reviews and status of the Branch's actions in addressing the recommendations.

a. Recommendation 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 of the 2004 IMPEP report)

May 2005 Status: A committee (comprised of licensing and inspection staff) meets monthly to review delinquent/unaccounted for licensees to determine what action should be taken. At the time of the review there were eight licensees that were identified for additional action. Division management has committed to providing investigative assistance from another branch under his supervision to assist in finding these licensees.

Current Status: Division management has assigned a special investigator to improve the capability of investigating missing and/or delinquent licensees. All previously unaccounted licensees have been located. With the additional assistance from the special investigator and process in place, the Branch has enhanced it ability to account for the whereabouts and security of radioactive material known to have existed under a license. The review team recommends that this item be closed.

b. Recommendation 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 of the 2004 IMPEP report)

May 2005 Status: Inspection findings are issued to licensees by the regional offices. Once the entire inspection package is completed (including all correspondence), it is provided to the Inspection, Compliance, and Enforcement (ICE) Supervising Health Physicist in Sacramento. In response to the recommendation, ICE has developed a database to track the timeliness of the correspondence sent to licensees. NRC staff reviewed the database and found that since the 2004 IMPEP review, 375 inspections have been completed with 19 inspection findings issued beyond 30 days. Overall, this represents good performance by ICE; however, the NRC staff noted that the database only documents the timeliness of these actions and does not provide an effective management tool for the ICE Supervising Health Physicist to track the progress of ongoing inspections. NRC staff noted that of the 19 late inspection findings transmitted by the regional offices, in eight cases, the findings were transmitted at least 57 days beyond the 30-day goal (average of 71 days with a range of 57 to 116 days). Seven of these eight cases were from one regional office (Los Angeles County). For the remaining 11 overdue inspection findings, the average time overdue was eight days (range of one to 25 days overdue).

Current Status: ICE has continued to monitor the issuance of inspections findings against the 30 day metric. Since January 2005, for 511 inspections only nine inspections findings were issued beyond 30 days. Branch management is continuing to monitor the on-going inspections and investigate root causes for the delays. The review team recommends that this item be closed.

c. Recommendation 4: The review team recommends that the incident and allegation history of a licensee be reviewed during evaluation of licensing actions. (Section 3.4 of the 2004 IMPEP report)

May 2005 Status: The Branch has modified their administrative process to add a comment on the master licensing list indicating if there is an open incident or allegation pending for any licensing action. This will allow the license reviewer to contact the ICE inspector or supervisor to determine if the license reviewer will need to take specific action during the review and amendment of the license. The master licensing list reflects incoming licensing actions by unit and type. Each action includes a comment line that reflects a brief summary of the action and any previous assignments of the action entered by the Special Projects and Support Unit. This list is used by the Senior Health Physicist to assign action to a reviewer. The Special Projects and Support Unit now compares the incoming license number to the 5010 database and identifies a match on the comment line. The modification to the master licensing list would now identify an open incident or allegation by including “5010 #xxx Health and Safety (H&S) or administrative.” The designation 5010 refers to the Form and database used to track a particular incident or allegation (specific number or “#xxx”) with an indication of its priority; either H&S or administrative. This modification to the master licensing list was first accomplished during the NRC staff’s on-site visit. The Branch plans to complete the procedure and evaluate feedback from licensing staff in June 2005.

Current Status: The 2006 review team noted in the review of the incident and allegation files that the license reviewers are reviewing the incident and allegation history during followup licensing actions since the May 2005 special review. The review team recommends that this item be closed.

d. Recommendation 9: The review team recommends that the Branch formally establish and implement (1) a process to notify the sealed source and device (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 of the 2004 IMPEP report)

May 2005 Status: NRC staff noted that the Branch modified their 5010 Form to allow the ICE staff to categorize a particular incident as an equipment problem or defect. As discussed above, individual incoming licensing actions on the licensing master list (which include amendments to SS&D registry sheets) are now noted with a particular 5010 reference number. This alerts the SS&D reviewer that an incident involving this device is still pending.

The Branch discussed with the NRC staff the status of guidance under development for SS&D reviewers to investigate reports of defects and incidents for root cause and generic implications. A draft procedure has been prepared by SS&D staff which has been reviewed by the SS&D Supervising Health Physicist. Once revised and finalized, the guidance will be implemented by staff by July 1, 2005.

Current Status: The 2006 review team noted the continuing use of the 5010 form to document all investigations which involve a SSD sheet issued by the Branch. The team was easily able to cross reference a investigation action with actions taken by the Branch SS&D Staff with the original investigation file and the completed form 5010. The procedure, however was not initiated until November 4, 2005, instead of the projected July 1, 2005, date noted above. During the reviews of the Technical Quality of Incident and Allegation Activities, the procedure was utilized appropriately. The review team recommends that this item be closed.

e. Recommendation 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. (Open recommendation from Section 4.2 of the 1996 report)

May 2005 Status: The Branch indicated that this registry sheet (CA-0380-D-101-G) has been modified to allow only distribution to specific licensees. NRC staff

reviewed the September 13, 2004, letter to Nova R&D from the Branch which reclassified the device to require distribution to only persons covered under a specific license. The SS&D evaluation certificate was also amended to reflect the required changes.

Current Status: The Branch initiated contact during the review with Nova R&D to determine their status on notification of all customers to whom the device was distributed. This was a requirement in the September 13, 2004, transmittal letter. Once the Branch has received information from the registrant, they plan to send letters to the appropriate NRC Region or Agreement State office to alert them to the possession of the device within their jurisdiction. The review team recommends that this item be closed.

2. Strengths and/or weaknesses of the State program as identified by the State including identification of actions that could diminish weaknesses.

The Acting Branch Chief identified the following as strengths of the Branch's program: strong management support; increased funding for training; ability to hire new staff; ability to reorganize programs; qualified and experienced staff; added investigator position; and improved capability of investigating missing and/or delinquent licensees. The following weakness were identified; laborious process for adopting regulations, inability to issue civil penalties; database tracking systems; and difficulty filling vacant positions with qualified individuals competitively.

3. Feedback on NRC's program as identified by the State and including identification of any action that should be considered by NRC.

The Branch is concerned about the workload that may be needed for the 160 Increased Controls inspections.

4. Status of State Program including:

a. Staffing and training: See Section 2.1.

b. Materials Inspection Program:

In May 2005, ICE reassigned inspectors from the Berkeley (now part of the Northern office) and Sacramento offices to perform overdue inspections in the Granada Hills office (now part of the Southern office). The Branch also reassigned licensing reviewers with inspectors' qualifications to assist in addressing the inspection backlog and open event reports in the Los Angeles County office. This was accomplished with overtime. The Branch is closely monitoring the status of inspections. There are no overdue inspections at this time.

c. Regulations and Legislative changes: See Section 3.1.

d. Program reorganizations: See Section 2.1.

e. Changes in Program budget/funding: See Section 2.1.

5. Event Reporting. See Section 2.2.

6. Response to Incidents and Allegations: See Section 2.2.

7. Information exchange and discussion:

a. Current State initiatives: Discussed in follow up IMPEP Review report.

b. State's mechanisms to evaluate performance:

Since the Branch was placed on heightened oversight in 2004, numerous audits of the program have been conducted. All inspector accompaniments have been completed as required.

In addition, the Branch is undergoing several initiatives to examine their business process and prepare a strategic plan for the Branch and its upcoming work. In addition, the Branch is in the process of improving or adding new data tracking systems. Currently, they are investigating the use of "off the shelf" data management systems along with improving their current programs.

California adequately protects sensitive material sent by NRC.

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: Merrvel Engineering — License No.: 03046
Date of Incident: 7/1/05 — Incident Log No.: NMED 060150
Investigation Date: 2/17/06 — Type of Incident: Lost/Stolen Material
Type of Investigation: Inspection

Comment:
Inspection was precipitated by non-payment of fees and lack of response by licensee to the fee notices. Branch response appears to exceed the 30 day timeliness goal of Branch's new procedure to account for the whereabouts and security of licensed materials known to have existed under a license.

File No.: 2
Licensee: Earth Science Consultants — License No.: 06775
Date of Incident: ½1/05 — Incident Log No.: NMED 060048
Investigation Dates: 4/24-25/05 — Type of Incident: Lost/Stolen Material
Type of Investigation: Telephone

Comment:
Branch has not completed information in NMED and closed the record.

File No.: 3
Licensee: Providence St. Joseph Medical Center — License No.: 0059-19
Date of Incident: 8/18/04 — Incident Log No.: NMED 040600
Investigation Dates: 8/20/04 — Type of Incident: Medical Event
Type of Investigation: Telephone & E-mail

Comment:
No documentation in file of Branch actions from 10/19/04 until 3/15/06.

File No.: 4
Licensee: Isotope Product Laboratories — License No.: 1509-19
Date of Incident: 9/15/05 — Incident Log No.: NMED 050739
Investigation Date: 10/20/05 — Type of Incident: Lost/Stolen Material
Type of Investigation: Telephone, E-mail, & NOV

File No.: 5
Licensee: Saddleback Memorial Hospital — License No.: 2652-30
Date of Incident: 1/24/05 — Incident Log No.: NMED 050236
Investigation Dates: 4/11/05, 4/18/05 — Type of Incident: Medical Event
Type of Investigation: Telephone & E-mail

File No.: 6
Licensee: Isotope Product Laboratories
Date of Incident: 6/16/05
Investigation Date: 6/16/05
License No.: 06795-19
Incident Log No.: NMED 050467
Type of Incident: Leaking Sources
Type of Investigation: Telephone & E-mail

File No.: 7
Licensee: Regents of the Univ. of California, LA
Date of Incident: 10/21/05
Investigation Date: 10/24/05
License No.: 1335-19
Incident Log No.: NMED 050798
Type of Incident: Leaking Source
Type of Investigation: Telephone & E-mail

File No.: 8
Licensee: University of California, Irvine
Date of Incident: 2/17/05
Investigation Date: 3/05
License No.: 1338-30
Incident Log No.: NMED 050165
Type of Incident: Leaking Source
Type of Investigation: On-site

Attachment

May 30, 2006, Email from Gary Butner
California Response to Draft IMPEP Report

ADAMS ACCESSION NO.: ML061560558

From: "Butner, Gary (DHS-RHB)" <GButner@dhs.ca.gov>
To: <kxs@nrc.gov>
Date: 05/30/2006 8:43:47 PM
Subject: IMPEP Follow-Up

Hi Kathleen,

Feel free to change the language as you see necessary. Let me know if you need anything more. You have my phone numbers.

Only one comment for clarification on (page 3) Recommendation 1: 3rd paragraph ; last two sentences, starts out "A recent realignment shifted"

Change to read:

A recent realignment in the Inspection, Compliance and Enforcement (ICE) Section separated X-ray inspection from the materials inspection program. The change creates a Section specifically for radioactive materials inspection and a new Section for machine inspection. The realignment allows for streamlining management and simplifying oversight of the radioactive materials inspection section.

Thanks
Gary

CC: "Butner, Gary (DHS-RHB)" <GButner@dhs.ca.gov>