



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 17, 2008

Bonita Sorensen, M.D.
Chief Deputy Director of Policy and Programs
California Department of Public Health
1615 Capitol Avenue, MS-0050
Sacramento, CA 95814

Dear Dr. Sorensen:

On June 23, 2008, 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 Agreement State Program adequate to protect public health and safety. The MRB found the California Agreement State Program not compatible with the U.S. Nuclear Regulatory Commission's (NRC) program due to a number of regulatory amendments that the California Program has not addressed. However, because of significant program improvements noted since the last review, the MRB discontinued the period of Heightened Oversight and initiated a period of Monitoring. Monitoring is an informal process that allows the NRC to maintain an increased level of communication with an Agreement State program. As part of the Monitoring process, NRC will conduct calls with the appropriate representatives from the California Radiologic Health Branch every 4 months.

Section 5.0, page 17, of the enclosed final report contains a summary of the IMPEP review team's findings and recommendations. We request your evaluation and response to the recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review of the California Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for April 2009.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

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

Enclosure:
California Final IMPEP Report

cc w/enclosure: See next page.

cc w/enclosure:

Gary W. Butner, Chief
California Radiologic Health Branch

James D. Boyd, Commissioner
California Energy Commission

William A. Passetti, FL
Organization of Agreement States
Liaison to the MRB



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE CALIFORNIA AGREEMENT STATE PROGRAM

March 31 - April 4, 2008

FINAL REPORT

Enclosure

1.0 INTRODUCTION

This report presents the results of the review of the California Agreement State Program. The review was conducted during the period of March 31 - April 4, 2008, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of New York. 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 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 of May 1, 2004, to April 4, 2008, were discussed with California management on the last day of the review.

The review team issued a draft report to the State on May 1, 2008, for factual comment. California responded to the findings and conclusions of the review by letter dated May 29, 2008, from Mr. Gary W. Butner, Acting Branch Chief, Radiologic Health Branch. On June 23, 2008, the Management Review Board (MRB) met to consider the proposed final report. The MRB found the California Agreement State Program adequate to protect public health and safety and not compatible with NRC's program. The MRB discontinued the period of Heightened Oversight and initiated a period of Monitoring.

The Radiologic Health Branch (the Branch), located within the Division of Food, Drug, and Radiation Safety (the Division), administers the California Agreement State Program. The Division is part of the Department of Public Health (the Department). Organization charts for the Department and the Branch are included as Appendix B.

At the time of the review, the California Agreement State Program regulated approximately 2,030 specific licenses. The review focused on the radioactive 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 preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Branch on January 9, 2008. The Branch provided its response to the questionnaire by e-mail on March 11, 2008. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML081130553.

The review team's general approach for conduct of this review consisted of: (1) examination of the Branch's response to the questionnaire; (2) review of applicable California statutes and regulations; (3) analysis of quantitative information from the Branch's database; (4) technical review of selected regulatory actions; (5) field accompaniments of eight of California's radioactive materials inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the California Agreement State Program's performance.

Section 2.0 of this report discusses the State's actions in response to open recommendations from previous IMPEP reviews. Results of the current review for the common performance indicators are presented in Section 3.0. Section 4.0 discusses the results of the review of the

applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the 2006 followup IMPEP review, which concluded on March 30, 2006, the review team kept open four recommendations from previous reviews. The current status of the recommendations is as follows:

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 of the 2006 followup IMPEP report)

Current Status: The review team recognized significant staffing improvements in the Branch since the followup review. The review team determined that the staffing, reorganizing, and realigning of the Branch enhanced the management oversight of the program. Even with the turnover that has occurred since 2006, the Branch was able to improve in the areas of inspection and licensing due to the improved management oversight. The current staff was able to sustain the inspection timeliness while absorbing the demand of the Increased Controls. This recommendation is closed.

2. The review team recommends that the Branch, in coordination with Idaho National Laboratory, complete and close all reportable incidents in NMED. (Section 2.2 of the 2006 followup IMPEP review report)

Current Status: The Branch has closed almost all of the previously identified open incident entries in the Nuclear Material Events Database (NMED). At the time of this review, the Branch had seven open reportable incidents, all of which were still under investigation. This recommendation is closed.

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 of the 2006 followup IMPEP review report)

Current Status: Following the 2004 IMPEP review, the Branch designed and implemented a database to track incident and allegation investigations to ensure timeliness, appropriate followup, and closure. The Branch also revised its policy on documenting investigations. The review team determined that, since implementation of the database, the Branch's performance with respect to tracking investigations has significantly improved. The review team noted that investigations are timely, well coordinated, and thoroughly documented and led to appropriate regulatory action. This recommendation is closed.

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 of the 2006 followup IMPEP review report)

Current Status: The review team recognized that progress has been made on addressing the issue of implementing State regulations to be compatible with NRC's program. The Branch's Regulations Unit has concentrated on developing proposed regulations that consolidate several of the earlier NRC amendments along with recent amendments when submitting the regulations through its rulemaking process. The Regulations Unit has also made efforts to streamline their regulation promulgation process by bringing responsibility for some of the processes that were performed by outside offices to the Branch. The streamlined process should reduce the amount of time it takes to promulgate a regulation by several months; however, the revised rulemaking process only applies to rulemaking initiated after March 2008. The Branch continues to have a significant number of outstanding regulations that have not been completed within the required 3-year period. For this reason, the review team recommends that this recommendation remain open. The current status of the State's rulemaking efforts is discussed in detail in Section 4.1.2 of this report.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing NRC Regional and Agreement State radioactive materials 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. The review team examined the Branch's questionnaire response relative to this indicator; interviewed Branch managers and staff; and reviewed job descriptions, training plans, and training records. The review team also considered any possible workload backlogs in evaluating this indicator.

The Branch is comprised of five Sections, all reporting to the Branch Chief. The Financial Operations and Analysis Section serves the program infrastructure and human resources. The Registration and Certification Section, and the Inspection, Compliance, and Enforcement Section, Radiation Machines, deal primarily with machine-made radiation. The Radioactive Materials Licensing Section (the Licensing Section) performs all of the Agreement State licensing functions. The Inspection, Compliance, and Enforcement (ICE) Section, Radioactive Materials, is the inspection arm of the Branch for the materials program.

The Licensing Section employs four Senior Health Physicists as supervisors of a Unit, and has staff positions for 21 Associate Health Physicists, one Assistant Health Physicist, and a newly added Junior Health Physicist. All licensing functions are performed in the Sacramento office, by three of the four Units in the Licensing Section. The fourth Unit supports the three licensing Units by performing radiological assessments.

The ICE Section is operated out of the Sacramento office and two regional offices, in Richmond (Northern California), and in Brea (Southern California), reorganized from four regional offices that existed during the 2006 followup IMPEP review. Each of the two regional offices has a Senior Health Physicist as a supervisor. The Northern California Office has four Associate

Health Physicists and two support staff, while the Southern California Office has three Associate and one Assistant Health Physicists. In addition, the Branch has contracts with Los Angeles and San Diego Counties to perform radioactive material inspections. A total of three full-time equivalents for radioactive materials inspections are currently contracted in the County programs. At the time of the review, the total number of health physicist positions dedicated to radioactive materials in the ICE Section was 12, not including contractor support.

A separate unit, the Regulations Unit, reports directly to the Branch Chief and is staffed by a Senior Health Physicist and an Associate Health Physicist that maintain the State's radioactive materials regulations.

At the time of the review, the Branch Chief position was staffed by an Acting Chief. In addition, the Assistant Branch Chief position was vacant. Discussions with managers above the Branch indicated that the Branch Chief position would be permanently filled in the near future and that the Assistant Branch Chief position would be filled soon after that. The current Acting Branch Chief is also the Section Chief for the Licensing Section. The Section Chief for the ICE Section is currently in the position on a limited-term assignment that expires in August 2008. The Branch intends to fill the position with a permanent staff member, rather than continuing with limited-term assignments. Of the 30 staff Health Physicist positions, three were vacant in the Radioactive Materials Licensing Section at the time of the review. The Branch has promptly posted and selected qualified staff when vacancies have occurred. The Branch had posted, interviewed, and, at the time of the review, was about to fill two of the vacant Associate Health Physicist positions, and to interview for an Assistant Health Physicist position. The Branch recently acquired a new position for a Junior Health Physicist, a position for a recent college graduate.

The review team determined that the balance in staffing the licensing and inspection programs was effective, because there are few vacancies in the staff positions. Management level vacancies were scheduled to be filled promptly. The review team determined actions taken by management in reorganizing and recruiting qualified individuals for vacancies have proven effective in decreasing the turnover rate and bringing stability to the staff. Despite the eleven departures, and the eight new or returning hires since the 2006 followup review, the Branch maintained or improved on the overall inspection status and licensing, as reflected in the other common indicators discussed below.

The review team reviewed job descriptions, qualification matrixes, and training records maintained by the inspection and licensing sections. The 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 was completed. The Branch documents the training requirements for license reviewers in Procedure 07-01, "Training Program for Radioactive Materials Licensing Health Physicists." Qualifications for license reviewers and inspectors are consistent with those found in NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Program Area." Currently, all license categories are covered by trained inspectors or license reviewers as indicated by the Branch's qualification records.

The review team recognized significant staffing improvements in the Branch since the 2006 followup IMPEP review. The review team believes that the combination of the fee package approved in 2005, the Branch's annual budget increase at that time, the reorganization and

realignment of the Branch, and the focus to promptly recruit for and fill staff positions has enhanced the overall management and performance of the program.

The review team discussed the role of the Nuclear Medicine Council (the 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. No evidence of any conflict of interest issues was identified.

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, was satisfactory.

3.2 Status of Materials Inspection Program

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

The review team verified that the Branch's inspection priorities, with the exception of high dose-rate remote afterloaders (HDR), are at the same frequency as similar license types found in NRC's IMC 2800, "Materials Inspection Program." The Branch inspects HDRs at 3-year intervals, which is inconsistent with the priority established in IMC 2800, Priority 2. The Branch based their HDR priority categorization on a 1998 evaluation of safety findings during inspections of HDRs. The Branch had not identified any significant violations with the operation of HDR units and established a written procedure to extend (or reduce) inspection intervals based on licensee performance. The review team recognized that this was identified as a good practice as a result of the 1999 IMPEP review. In 2003, the NRC reevaluated and updated its inspection priorities in IMC 2800, including changing HDRs from Priority 1 licensees to Priority 2 licensees, as well as eliminated the practice of extending inspection intervals based on licensee performance. In light of the changes to IMC 2800 and the changes to policies on the security of radioactive materials, the review team concluded that the Branch's justification for inspecting HDR licensees on a 3-year interval may no longer be acceptable. The review team recommends that the State reevaluate its justification for inspecting HDR licensees on a 3-year interval and demonstrate that the health, safety, and security of HDR devices are not compromised.

The review team determined that during the review period, the Branch conducted approximately 935 Priority 1, 2, and 3 inspections, based on the inspection frequencies specified in IMC 2800. During the review period, the Branch completed 139 of these inspections overdue. However, the review team identified no overdue inspections at the time of the review. Additionally, the Branch completed 316 initial inspections, of which 16 were conducted overdue (greater than 12 months after license issuance), and the review team identified 5 as overdue at the time of the review. Overall, the Branch performed approximately 12.5 percent of the total Priority 1, 2, and 3 and initial inspections overdue during the review period. Discussions with Branch managers revealed that they decided to allow some routine inspections to go overdue in order to ensure the timely completion of initial Increased Controls inspections.

The review team noted that the guidance in the Office of Federal and State Materials and Environmental Management Programs (FSME) Temporary Instruction TI-002, "Integration of the Increased Controls into IMPEP," allows the review team to provide flexibility when calculating overdue routine inspections, if routine inspections were deferred in order to complete the initial Increased Controls inspections in a timely manner. To be provided this flexibility, a program must have a documented plan for completion of the deferred inspections. The Branch provided their methodology for inspection prioritization and presented a documented plan demonstrating the completion of all deferred inspections. With the consideration of the deferred routine inspections, the review team calculated that the Branch would have only performed approximately 3 percent of its Priority 1, 2, and 3 and initial inspections overdue.

The review team evaluated the Branch's timeliness in providing inspection findings to licensees. The Branch's database contains tracking information on correspondence for all types of inspections, including initial inspections, routine inspections, followup inspections, Increased Controls inspections, and reciprocity inspections. The review team determined that over the review period approximately 92 percent of all correspondence related to inspection findings were communicated to licensees in less than 30 days.

During the review period, the Branch granted 210 reciprocity permits, 95 of which were candidate licensees based upon the criteria in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." The review team determined that the Branch met and/or exceeded the criterion of inspecting 20 percent of candidate licensees operating under reciprocity, as prescribed in IMC 1220, in each of the 4 years covered by the review period.

The review team determined that the Branch adequately planned for the initial set of Increased Controls inspections. The review team evaluated the Branch's prioritization methodology and found it acceptable. The Branch identified a total of 140 licensees subject to the Increased Controls, of which 55 were found to be higher risk licensees and were inspected within the first year. The Branch completed 91 percent of all initial Increased Controls inspections as of the date of the review and had only 12 Increased Controls inspections left to perform by June 2009.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that California's performance with respect to the indicator, Status of Materials Inspection Program, was satisfactory.

3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 32 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by 15 inspectors and covered a wide variety of inspection types, including: broad scope medical, portable gauge, industrial radiography, self-shielded irradiator, service provider, research and development, nuclear pharmacy, Increased Controls, and reciprocity. This evaluation included a review of documentation for decommissioning-in-process inspections and confirmatory surveys performed by the Radiological Assessment Unit. Appendix C lists the inspection casework files reviewed, as well as the results of the inspector accompaniments.

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

The Branch's inspection procedures are, for the most part, consistent with the inspection guidance found in IMC 2800. The Branch has a goal of performing 90 percent of its inspections unannounced, but allows one-day announcements to increase inspector efficiency. The ICE Section Chiefs review all inspection reports. Once signed, completed reports are promptly issued. Alternatively, the inspector may opt to provide inspection results to the licensee utilizing a Branch 8385 "short" form, which is left with the licensee at the completion of the onsite inspection. The review team found that inspection findings were clearly stated and documented. The review team noted that, with one exception, inspection correspondence involving the Increased Controls was appropriately labeled as sensitive information and withheld from public disclosure.

The Branch requires licensees to respond to all Notices of Violation within 30 days of issuance. Licensee responses are reviewed for adequacy by the inspector and an ICE Section Chief. An acknowledgment letter is then sent to the licensee.

During the review period, ICE Section Chiefs or designated Senior Inspectors performed annual accompaniments of all individuals who performed radioactive materials inspections. The accompaniment reports contained sufficient details to document the areas covered.

The review team verified that the Branch maintains an adequate supply of appropriately calibrated survey instrumentation, which is capable of detecting a wide variety of radiological conditions and isotopes, to support its inspection program, as well as to respond to radioactive materials incidents and emergency conditions. The review team's interviews with staff revealed a good understanding of survey instrument use.

The review team reviewed the State laboratory facility to evaluate its support to the Branch. The State laboratory is located adjacent to the Branch's Northern California Office and performs sample analyses for multiple programs within the Branch. The laboratory employs 23 staff members, of which 4 are dedicated to radiochemistry analysis. One staff member's position is funded entirely by the Branch. The laboratory has a wide array of analytical equipment capable of detailed radiochemistry analysis including multiple high purity germanium detectors, several gamma counters, and various scintillation counters. Samples are analyzed for the Branch 2-3 times monthly and generally include wipe analysis and analysis of samples from items found in the public domain.

The review team accompanied eight inspectors during the weeks of January 28, 2008, and February 25, 2008. Inspectors conducted inspections at hospitals, medical offices, a nuclear pharmacy, a radiography facility, and a portable gauge facility. Inspectors demonstrated appropriate performance-based inspection techniques and adequate knowledge of the regulations. The inspectors were well trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews

with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The review team determined that the inspections performed were adequate to assess radiological health, safety, and security.

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 Inspections, was satisfactory.

3.4 Technical Quality of Licensing Actions

The review team evaluated the licensing process, examined licensing casework for 27 specific licenses, and discussed licensing issues with staff. 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, Increased Controls requirements, 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 selected provided a representative sample of licensing actions that were completed during the review period. The sampling included the following types: medical institution, medical private practice, nuclear pharmacy, veterinary, industrial radiography, irradiator, decommissioning, fixed and portable gauge, decontamination service, research and development, and well logging. Casework included 7 new licenses, 4 renewals, 4 terminations, and 12 amendments. Eight of these cases included a review of the applicability of the Increased Controls. A listing of the licensing casework evaluated, with case-specific comments, can be found in Appendix D.

All licensing actions are performed in the Sacramento office by the Licensing Section. The Licensing Section includes the Medical Unit, the Industrial and General Licensed Device Unit, the Projects Unit, the Radiological Assessment Unit, and a financial assurance specialist. In the Medical Unit, the Senior Health Physicist assigns licensing actions once per week to the license reviewers. The license reviewers in the Industrial and General Licensed Device Unit select licensing actions from an updated printout of pending actions. License reviewers in the Projects Unit select licensing actions from updated printout of unassigned licensing actions. The Unit's Senior Health Physicist assigns actions that remain on the unassigned printout for approximately one week. The status of all licensing actions is tracked with a database.

The Licensing Section generates licenses and correspondence with standardized conditions and formats. Licensing actions are reviewed by a peer and are forwarded to the applicable Unit Senior Health Physicist for final review and signature. The Medical Unit has developed multiple licensing guides based on the NRC NUREG-1556 Series, "Consolidated Guidance About Materials License," as well as licensing guidelines for emerging technologies. License review guidance documents/procedures, as well as checklists, are provided, and in general, reviewers use these tools. The license reviewers review each inspection file prior to reviewing renewal applications to determine the inspection and enforcement history of the licensee.

The review team reviewed decommissioning actions involving licensees removing a building or location of use from their license. The review team found that decommissioning licensing actions were well documented, showing appropriate transfer records and/or appropriate disposal methods and records, confirmatory surveys, and survey records. Terminated licensing actions were well documented, showing appropriate transfer and survey records. 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 stated regulatory positions, were used at the proper time, and identified deficiencies appropriately. A complete renewal application is required every ten years. A License Expiration Notice directs licensees to request any significant changes to the radiation protection program under separate cover. The Senior Health Physicists perform a cursory review of renewal applications to identify any health and safety items that need prompt licensing action, such as a change in radiation safety officer or use of licensed materials. The backlog of renewal actions has steadily increased during the review period to approximately 350 renewal applications. At the time of the review, the Branch was in the process of filling several license reviewer vacancies. The review team did not identify any health and safety impact caused by the backlog of renewal applications.

The review team reviewed license files to verify incorporation of the serialization requirements from the Title 10 Code of Federal Regulations (CFR) Part 32 rule amendment and the Increased Controls requirements (NRC Order EA-05-090) via license conditions. The review team found that one of three licenses reviewed for manufacturers of sealed sources did not include the appropriate license condition for serializing sources. The review team notified Branch managers and the Branch immediately modified the license to incorporate the license condition. All licenses reviewed for the Increased Controls included the proper license condition.

The review team determined that license reviewers applied pre-license screening guidance to the applicants for new licenses. For two of the seven new license applicants, the Branch conducted pre-licensing inspections.

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 Licensing Actions, was satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Branch's actions in responding to incidents and allegations, the review team examined the Branch's response to the questionnaire relative to this indicator, evaluated selected incidents reported for California in NMED against those contained in the Branch's files, and evaluated the casework for 15 radioactive materials incidents. A listing of the casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Branch's response to eight allegations involving radioactive materials, seven of which the NRC referred to the State during the review period.

When the Branch is notified of an incident or allegation, the staff member who receives the notification fills out a Form 5010, "Matter Requiring Investigation/Inspection." A manager assigns responsibility for initial response to incidents and allegations involving radioactive

material, both falling under the category of “investigations,” to a technical staff member. The Branch has comprehensive written procedures for handling investigations. Once the investigation is completed, a “Materials Investigation Closing Memo” is generated, signed off by the appropriate manager, and placed in the investigation file. The investigation is not considered complete until a Senior Health Physicist performs a quality assurance/quality control review of the file. The review team noted that the entire process can take up to 180 days.

The incidents selected for review included medical, lost/stolen radioactive material, leaking source, damaged equipment, and equipment failure. The review team determined that the Branch’s responses to incidents were complete and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. At the conclusion of the investigation, the inspector generates a narrative report that thoroughly documents the investigation. In most cases, the Branch dispatched inspectors to the site in response to incidents; however, the investigation files did not always clearly indicate if an on-site investigation was conducted. The review team discussed the benefits of documenting that on-site investigations were conducted. The Branch indicated that the template for the investigation narratives could be modified to include additional discussion on the State’s actions in response to incidents and allegations.

The review team identified 263 California byproduct material incidents in NMED, since the 2006 followup IMPEP review, of which 169 required reporting to the NRC Headquarters Operations Center. The review team evaluated the Branch’s reporting timeliness to the NRC Headquarters Operations Center, and determined that, following notification from the licensee, the Branch reported most incidents within the required time frame. The Branch submits all 24-hour reportable events to the NRC Headquarters Operations Center by telephone, fax, or e-mail. In some cases, the Branch may provide a copy of the Form 5010 as part of this event reporting. Due to software compatibility issues, the Branch does not directly input event information into NMED using the NMED software. Instead, the Branch furnishes their Form 5010 event information to the NRC’s NMED contractor. The Branch provides updates for the NMED entries, as needed, directly to the NRC’s contractor responsible for maintaining NMED. The review team found that incident information in NMED for California incidents was complete and up to date. The Branch plans to use the next generation of NMED software upon release.

In evaluating the effectiveness of the Branch’s response to allegations, the review team evaluated the casework for eight allegations, seven of which the NRC referred to the State during the review period. The review team concluded that the Branch generally took prompt and appropriate action in response to concerns raised. The review team identified two additional allegations that the NRC referred to the State during the review period. The Branch was unaware of one of the allegations and had not entered the other into their tracking system in a timely manner. The review team provided the Branch with the information regarding the two allegations. The Branch immediately entered the allegation information into its tracking system. Both allegations involved alleged illegal distribution of radioactive product via on-line retailers. The review team determined that a contributing factor was the communication of the allegations from the NRC to the State. The review team and Branch managers discussed this issue and agreed to include several key individuals on the distribution of the allegation information to resolve the issue.

With the exception of those allegations pending investigation, the review team noted that the Branch thoroughly documented the investigations and retained all necessary documentation to

appropriately close the allegations. The Branch notified affected individuals of the actions taken in cases where a notification was requested.

The State has a Freedom of Information Act-equivalent law, the Public Records Act. The review team discussed the Branch's process for release of records under the Public Records Act and determined that the alleged identities were adequately protected.

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, was satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing 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 relinquish authority for a Uranium Recovery Program; therefore, 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 on September 1, 1962. The statutory authority for the State's radiation control program is found in Radiation Control Law contained in Division 20, Section 7.6 of the California Health and Safety Code. The Division is designated as the State's radiation control agency, and the Branch implements the radiation control program. The review team noted that no legislation affecting the radiation control program was passed during the review period.

4.1.2 Program Elements Required for Compatibility

The regulations for the control of radiation (from radioactive material and machine) are contained in Title 17 (Public Health), Division 1, Chapter 5, Subchapter 4 of the California Code of Regulations. The Branch requires an entity to have a license for possession and use of all radioactive material, including naturally-occurring materials, such as radium, and accelerator-produced radionuclides.

The review team evaluated the Branch's response to the questionnaire relative to this indicator, 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 sheet maintained by FSME.

A review of the State's rulemaking process revealed that the process can take over 600 days after preparation of a draft rule to the final filing with the Secretary of State, after which the rule becomes effective in 30 days. The public, NRC, other State agencies, and all potentially impacted licensees and registrants are offered an opportunity to comment during the rulemaking review process. When the proposed rule is sent for public comment, it is also sent to NRC for a

compatibility review. After resolution of any comments received, the final rules are noticed in the *California Register* and are provided to the licensees and the NRC. With the above-stated lead time needed, the Branch must initiate its rulemaking process for those rules necessary for compatibility immediately after NRC publishes its final rule in order to meet the 3-year requirement for compatibility.

The State can adopt other agency regulations by reference, but the review team noted that State regulations need to pass their criterion called clarity, in that the regulation needs to be clear, difficult to misunderstand, and be stand-alone (no guidance needed). The State has difficulty at times incorporating NRC rules by reference because NRC regulations tend to be performance-based, with implementing guidance available in other documents. The State would have to incorporate the applicable guidance in its regulations to pass the clarity criterion.

At the time of the 2006 followup IMPEP review, the Branch had 19 overdue regulations. During the last 2 years, the Branch completed five required amendments either through rulemaking or implementation through alternate legally binding requirements. Of the five adopted amendments, four were overdue, and one addressed a future amendment. With the addition of two regulations that have come due since 2006, there were 17 overdue amendments at the time of the review.

The Branch has four packages that are currently outside the Branch going through the State's rulemaking process. These four packages cover a total of 10 overdue amendments (two in transportation, five in industrial radiography, one in financial assurance, and two in a combined rule package).

The review team noted that the Regulations Unit that processes the regulations for the Branch has made efforts to streamline the rulemaking process by performing some of the work normally performed outside their Branch. This process change should eliminate several months of out-of-office processing time. The benefits of this effort should be seen in future IMPEP reviews. The current staffing level in the Regulations Unit dedicated to the materials regulation development program is not sufficient to complete the overdue regulations and keep current on the newer regulation development needs. During the on-site review, Branch management indicated that they are considering adding resources in this area.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after they become effective. The following 13 amendments are overdue for adoption, some significantly longer than 3 years from their effective date. The current status for each amendment is:

- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104), that was due for Agreement State implementation on January 27, 1995.

Status: Draft in the Branch.

- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Part 30, 40, and 70 amendments (59 FR 36026), that was due for Agreement State implementation on August 15, 1997.

Status: This rule is tied to the amendment "Radiological Criteria for License Termination." See below.

- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Part 20 and 35 amendments (60 FR 48623), that was due for Agreement State implementation on October 20, 1998.

Status: The 10 CFR Part 20 portion of this rule was adopted by the State on September 10, 1998. Draft package to address 10 CFR Part 35 portion in Branch.

- "10 CFR Part 71: Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248), that was due for Agreement State implementation on April 1, 1999.

Status: Package with California Health and Human Services.

- "Recognition of Agreement State Licenses in Areas under Exclusive Federal Jurisdiction within an Agreement State," 10 CFR Part 150 amendment (62 FR 1662), that was due for Agreement State implementation on February 27, 2000.

Status: Package with California Office of Legal Services.

- "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Part 20 and 35 amendments (62 FR 4120), that was due for Agreement State implementation on May 29, 2000.

Status: The 10 CFR Part 20 portion of this rule was adopted by reference in 1998. Draft of the 10 CFR Part 35 portion in Branch.

- "Radiological Criteria for License Termination," 10 CFR Part 20, 30, 40, and 70 amendments (62 FR 39057), that was due for Agreement State implementation on August 20, 2000.

Status: The 10 CFR Part 20 portion of the regulation was adopted and then 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 is currently terminating licenses on a case-by-case basis. The Department is considering options to address this regulatory issue.

- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Part 20, 35, and 36 amendments (63 FR 39777 and 63 FR 45393), that was due for Agreement State implementation on October 26, 2001.

Status: The 10 CFR Part 20 portion of this rule was adopted by reference in 1998. The 10 CFR Part 35 changes will be addressed as part of the Part 35 draft package that is with the Branch. The 10 CFR Part 36 portion was incorporated by reference to Federal regulations via license condition.

- “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR Part 30, 31, and 32 amendments (65 FR 79162), that was due for Agreement State implementation on February 16, 2004.

Status: Package with California Office of Legal Services.
- “Medical Use of Byproduct Material,” 10 CFR Part 20, 32, and 35 amendments (67 FR 20250), that was due for Agreement State implementation on October 24, 2005.

Status: Draft package in Branch.
- “Financial Assurance for Materials Licensees,” 10 CFR Part 30, 40, and 70 amendments (68 FR 57327), that was due for Agreement State implementation on December 3, 2006.

Status: Package with California Health and Human Services.
- “Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments,” 10 CFR Part 71 amendment (69 FR 3697), that was due for Agreement State implementation on October 1, 2007.

Status: Package with California Health and Human Services.
- “Medical Use of Byproduct Materials - Recognition of Specialty Boards - Part 35,” 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926), that was due for Agreement State implementation on April 29, 2008.

Status: Draft package in Branch.

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

- “National Source Tracking System,” 10 CFR Part 20 amendment (71 FR 65865, 72 FR 59162), that is due for Agreement State implementation by January 31, 2009.
- “Minor Amendments,” 10 CFR Part 20, 30, 32, 35, 40, and 70 amendments (71 FR 15005), that is due for Agreement State implementation by March 27, 2009.
- “Medical Use of Byproduct Material – Minor Corrections and Clarification,” 10 CFR Part 32 and 35 amendments (72 FR 45147, 54207), that is due for Agreement State implementation by October 29, 2010.
- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Part 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72FR 55864), that is due for Agreement State implementation by November 30, 2010.
- “Exemption From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Part 30, 31, 32, 150 amendments

(72 FR 58473), that are due for Agreement States implementation by December 17, 2010.

- “Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,” 10 CFR Part 19 and 20 amendments (72 FR 68043), that is due for Agreement State implementation by February 15, 2011.

Considering the number of overdue regulation changes and the lengthy process to complete regulation promulgation, the review team was not able to find the California Agreement State Program as meeting the compatibility requirements under the IMPEP evaluation criteria. The review team believes that additional time and actions are needed before the State can adopt all overdue regulations required for compatibility; therefore, the review team is recommending that the recommendation for the 2006 followup IMPEP review remain open. 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.

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, was unsatisfactory.

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

In reviewing this indicator, the review team used three subelements to evaluate the Branch’s performance regarding the SS&D Evaluation Program. The subelements are: (1) Technical Staffing and Training, (2) Technical Quality of the Product Evaluation Program, and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Branch’s SS&D evaluation activities, the review team examined information provided by the Branch in response to the IMPEP questionnaire for this indicator. The review team conducted a review of all new, amended, and inactivated SS&D evaluations and supporting documents covering the review period. The review team noted the staff’s use of guidance documents and procedures, interviewed the staff involved in SS&D evaluations, and verified the use of regulations, license conditions, and inspections to enforce commitments made in the applications.

4.2.1 Technical Staffing and Training

Since the last review, nine members of the Branch have conducted SS&D evaluations. Five individuals were fully qualified SS&D reviewers with full signature authority; the others were partially qualified, or in training, and performed the initial reviews for the safety evaluations. Three of the fully qualified reviewers left the program during the review period.

The Branch’s comprehensive training program is discussed in detail in Section 3.1 of this report. The Branch has a documented qualification program for SS&D reviewers as a subsection of its qualification procedure. The Branch maintains a qualification journal for all reviewers, which lists the completed course work relevant to SS&D evaluations.

The Branch had a list of 15 open cases under timely review. The review team determined that the number of open cases, in light of the large number of SS&D cases that the Branch handles

on a yearly basis, is acceptable. Consequently, the review team determined that the staffing level dedicated to performing SS&D evaluations is adequate.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Branch completed 84 SS&D actions, which included new source and device evaluations, amendments of previously issued registrations, and inactivations of registration certificates. The casework reviewed included 22 of these actions. The cases selected for review were chosen to be representative of the work performed by the Branch during the review period, taking the following factors into account: the types of actions performed, the pool of licensees, the types of products evaluated, and the different reviewers who performed SS&D evaluations. A listing of the SS&D certificates evaluated, with case-specific comments, can be found in Appendix F.

Analysis of the casework and interviews with the staff confirmed that the Branch follows the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, Revision 1, "Consolidation Guidance About Materials Licenses: Application for Sealed Source and Device Evaluation and Registration." Appropriate review checklists were used to ensure all relevant materials had been submitted and reviewed. The checklists were retained in the SS&D files. The review team verified that pertinent American National Standards Institute standards, Regulatory Guides, and applicable references were available and were used when Branch staff performed SS&D reviews.

The review team determined that the registration files contained all correspondence, photographs, engineering drawings, radiation profiles, and details of the applicant's quality assurance and quality control program. 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 found that the evaluations were of high quality with health and safety issues properly addressed.

The review team noted some administrative issues and practices that differ from those used in the SS&D community in general. These issues and practices are noted in Appendix F as comments for each of the cases that were reviewed. Some of these issues were observed to be repetitive, such as the lack of protection of proprietary information, incomplete review of the quality assurance measures for products manufactured overseas, and the practice of listing the nominal value of isotope activity in place of the maximum value. The review team noted that safety issues were not affected by any of these administrative issues and practices.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Utilizing NMED and the Branch's response to the questionnaire, the review team examined a selected sample of incidents or failures regarding SS&D registered products that occurred during the review period. The review examined events that occurred within the State of California, as well as events nationwide that occurred within the review period involving equipment or sources registered by the Branch.

The Branch developed a comprehensive procedure to conduct safety evaluations of SS&D events and incidents (Procedure No. 04-03-005). The procedure addresses the entire

evaluation process in a highly comprehensive manner. For example, the procedure defines the roles and responsibilities for the supervisor and for the staff; delineates how to interface with other organizations; describes how to conduct the investigation for the event; and specifies the documentation requirements. The review team believes that such a procedure can help a program ensure completeness of technical reviews of SS&D incidents, including identification of generic issues. The review team recommended, and the MRB agreed, that the Branch's comprehensive procedure for conducting safety evaluations of SS&D events and incidents was a good practice. The review team determined that the Branch followed the procedure, analyzed the events, reviewed the issues, followed up on the incidents that were relevant to SS&D issues, documented the issues, and documented closure.

The Branch maintains files on SS&D events. The Branch processed 27 events during the review period. The review team selected and reviewed 16 of the events. A listing of the SS&D events reviewed by the review team, with case-specific comments, can be found in Appendix E. The files contained the documentation that was specified in the Branch procedure. The issues were resolved in accordance with the regulatory requirements and the relevant guidance documents and procedures. In cases where other Agreement States or the NRC were affected, the Branch took the appropriate action to contact the States or the NRC and requested followup action. One of the events involving equipment failure within the period was determined to be a generic issue. Regarding this generic issue, the Branch conducted inspections within California to obtain additional information and worked with the NRC in the development of NRC Information Notice (IN) 2007-35, "Varian Medical Systems Varisource HDR Events: Iridium-192 Source Pulled from Shielded Position." The Branch sent the IN to its licensees via Radiation Safety Advisory 08-01, "Radiation Hazard Event Reports with the Varisource HDR Device," which also included supplemental information.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that California's performance with respect to the indicator, SS&D Evaluation Program, was 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 Regulatory 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 Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although the California Agreement State Program has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a 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. At this time, there are no plans for a commercial LLRW disposal facility in California. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0, California's performance was found satisfactory for six performance indicators and unsatisfactory for the indicator, Compatibility Requirements. The

review team made two recommendations regarding the performance of the California Agreement State Program and identified one good practice. Accordingly, the review team recommended, and the MRB agreed, that the California Agreement State Program is adequate to protect public health and safety and not compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the period of Heightened Oversight of the California Agreement State Program be discontinued and that a period of Monitoring be initiated. Monitoring is an informal process that allows the NRC to maintain an increased level of communication with an Agreement State program. As part of the Monitoring process, NRC will conduct calls with the appropriate representatives from the California Agreement State Program every 4 months. The review team recommended, and the MRB agreed, that the next full IMPEP review of the California Agreement State Program will take place in approximately 4 years, with a periodic meeting in 1 year.

Below are the recommendations, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by the State.

1. The review team recommends that the State reevaluate its justification for inspecting HDR licensees on a 3-year interval and demonstrate that the health, safety, and security of HDR devices are not compromised. (Section 3.2)
2. 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)

Below is the good practice, as mentioned earlier in the report:

The Branch developed a comprehensive procedure to conduct safety evaluations of events and SS&D incidents (Procedure No. 04-03-005). The procedure addresses the entire evaluation process in a highly comprehensive manner. For example, the procedure defines the roles and responsibilities for the supervisor and for the staff; delineates how to interface with other organizations; describes how to conduct the investigation for the event; and specifies the documentation requirements. The review team believes that such a procedure can help a program ensure completeness of technical reviews of SS&D incidents, including identification of generic issues.

LIST OF APPENDIXES AND ATTACHMENT

Appendix A	IMPEP Review Team Members
Appendix B	California Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	Sealed Source and Device Casework Reviews
Attachment	May 29, 2008, Letter from Gary W. Butner California's Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Dennis Sollenberger, FSME	Team Leader Technical Staffing and Training Compatibility Requirements
Joseph DeCicco, FSME	Team Leader in Training Technical Staffing and Training Compatibility Requirements
Randy Erickson, Region IV	Status of Materials Inspections Inspector Accompaniments
Orysia Masnyk Bailey, Region I	Technical Quality of Inspections
Robert Dansereau, New York	Technical Quality of Licensing Actions
Aaron McCraw, FSME	Technical Quality of Incident and Allegation Activities
John Jankovich, FSME	Sealed Source and Device (SS&D) Evaluation Program

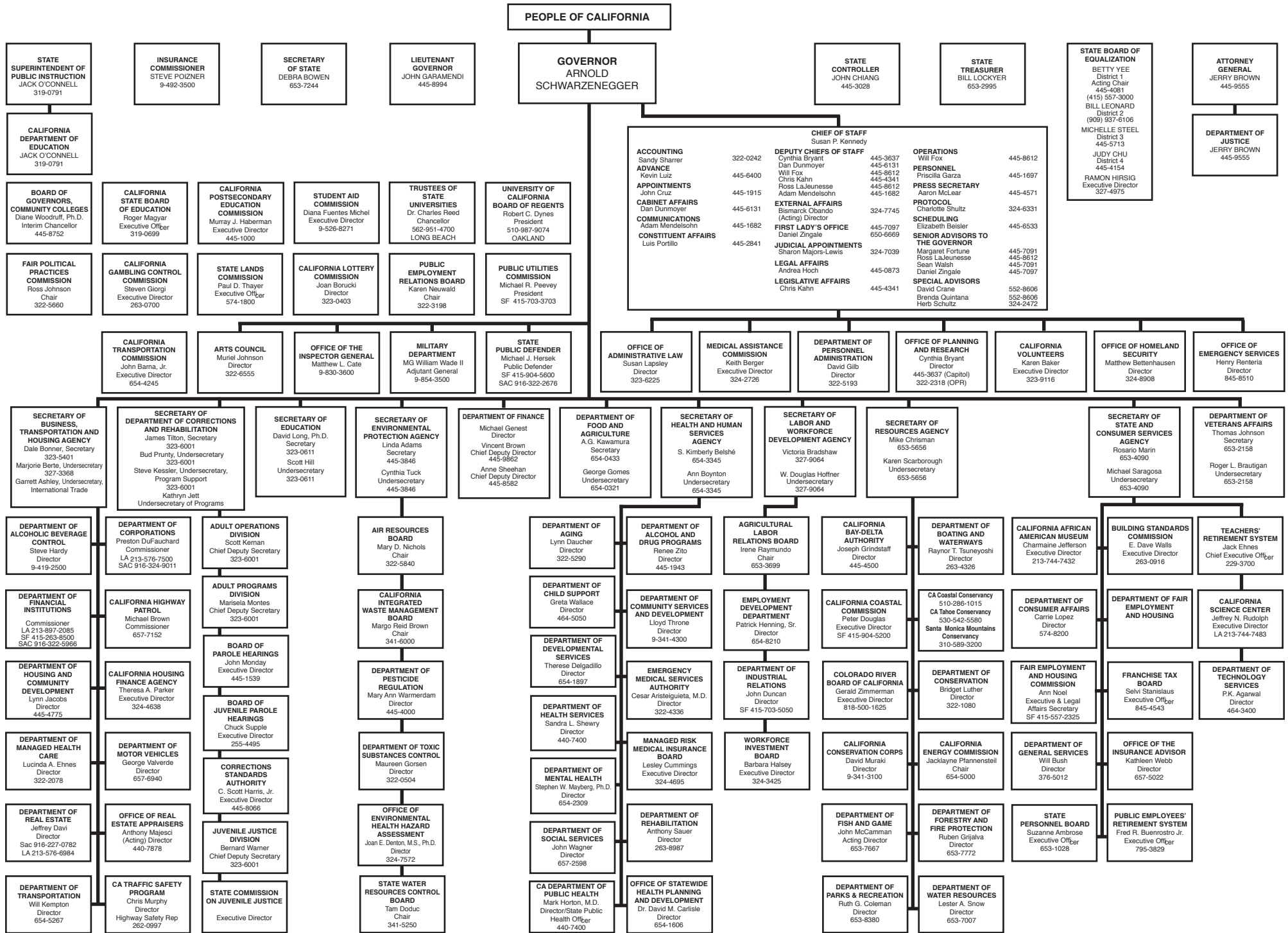
APPENDIX B

CALIFORNIA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML081130553

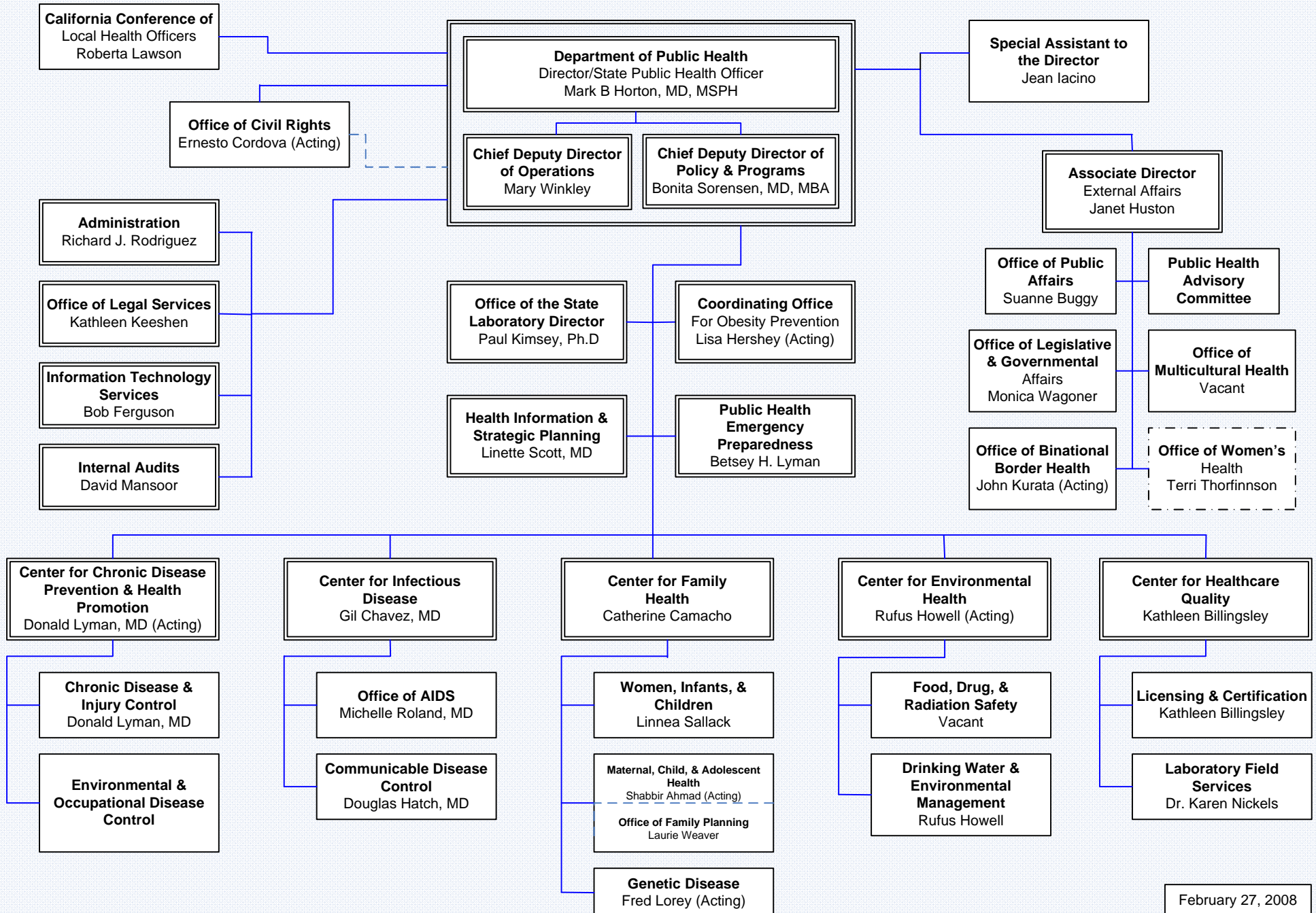
PAGES 15-23

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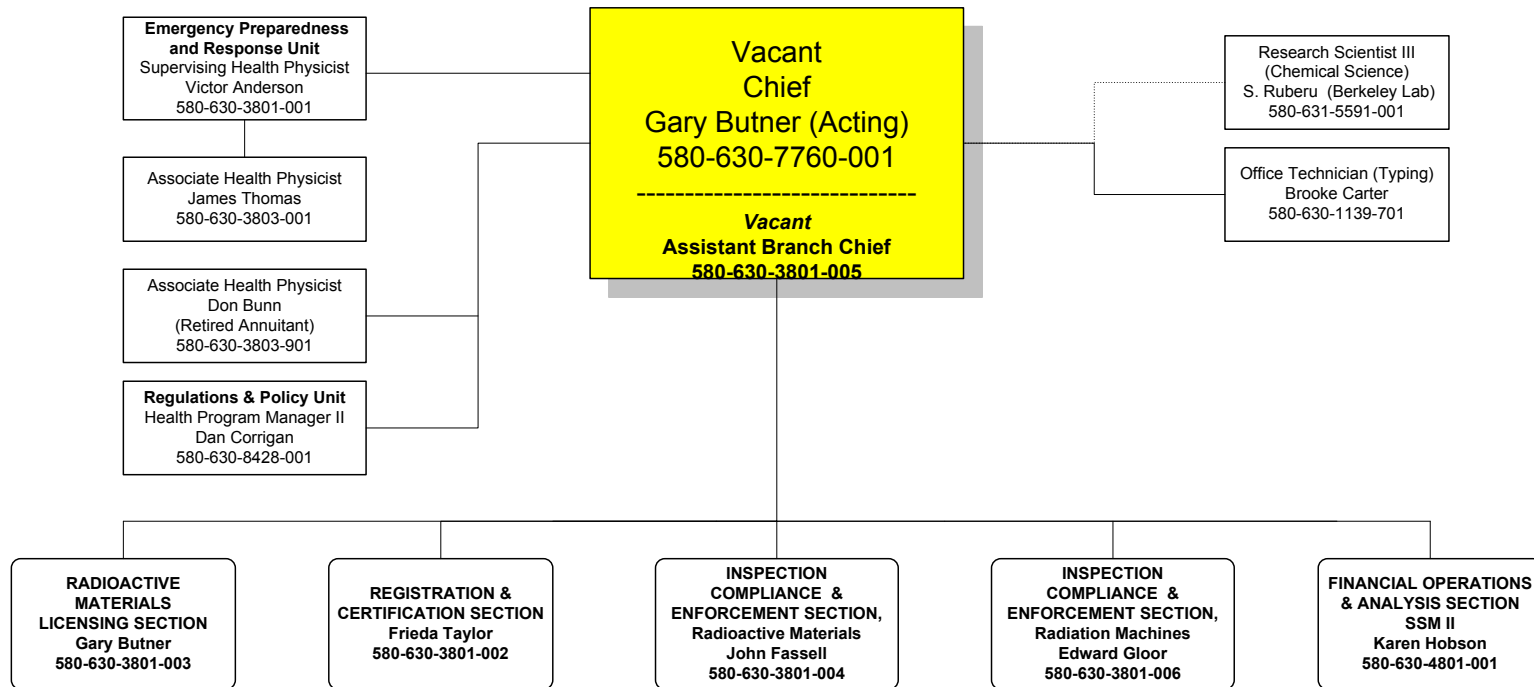


California Department of Public Health



February 27, 2008

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

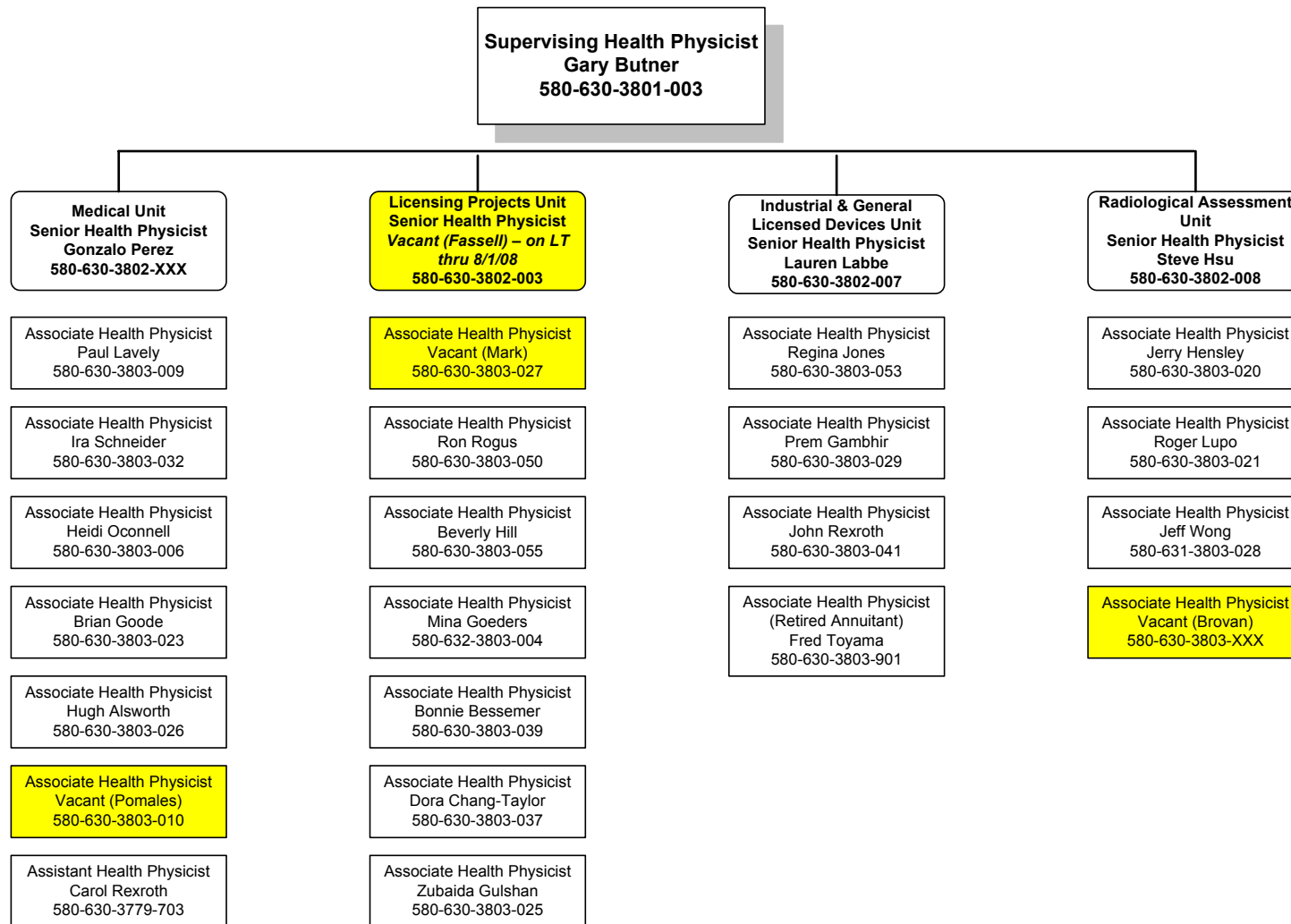


Approved:

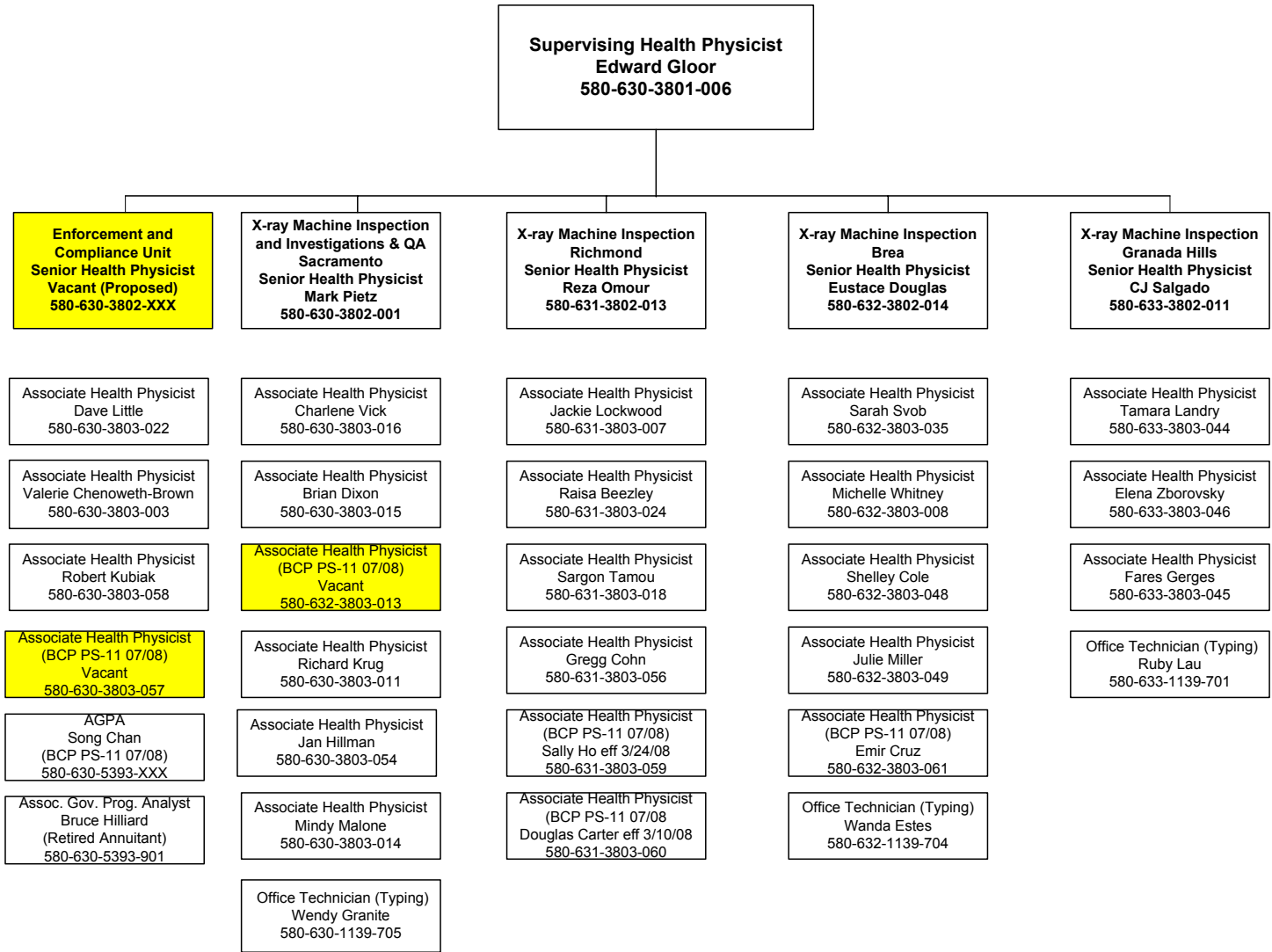
Gary Butner, Acting Branch Chief

Drew Johnson, Acting Division Chief, Food, Drug & Radiation Safety

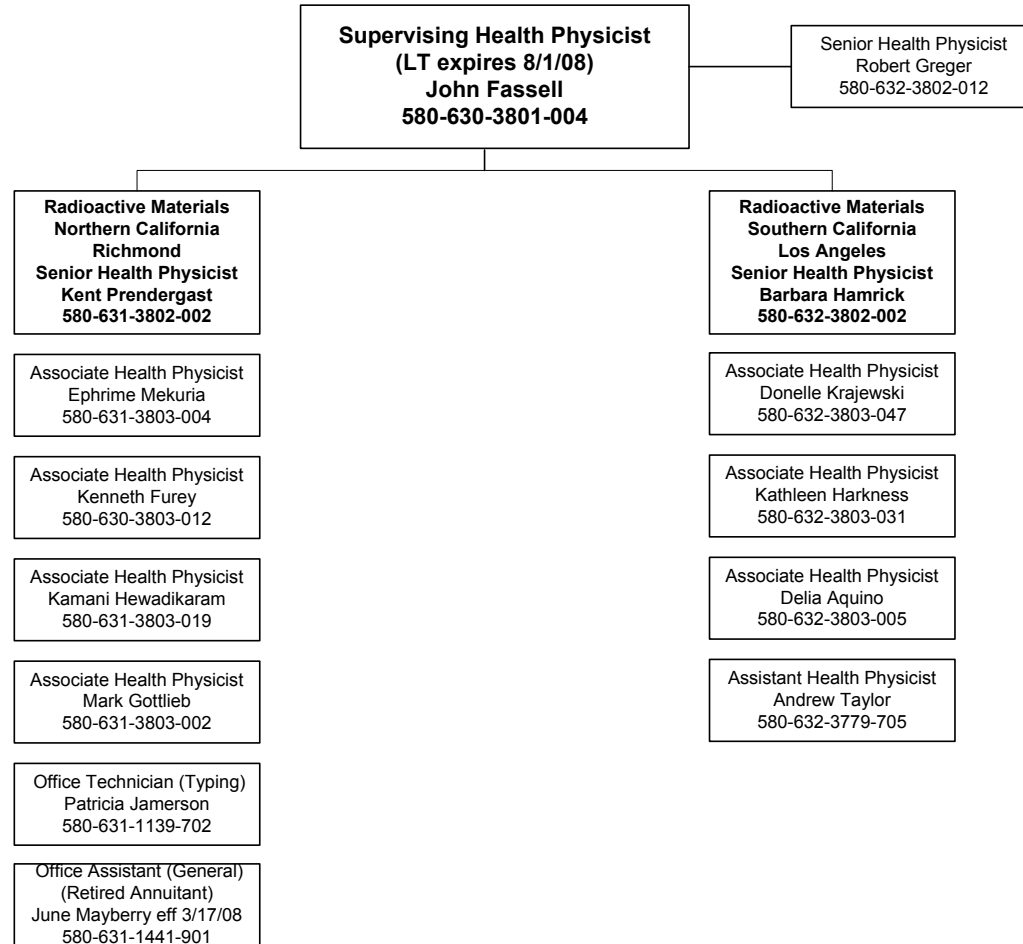
Radioactive Materials Licensing Section



Inspection, Compliance and Enforcement Section, Radiation Machines



Inspection, Compliance and Enforcement Section, Radioactive Materials



Regulations Unit

Health Program Manager II
Dan Corrigan
580-630-8428-001

Senior Health Physicist
Phillip Scott
580-630-3802-006

Associate Health Physicist
Leo Spencer
580-630-3803-051

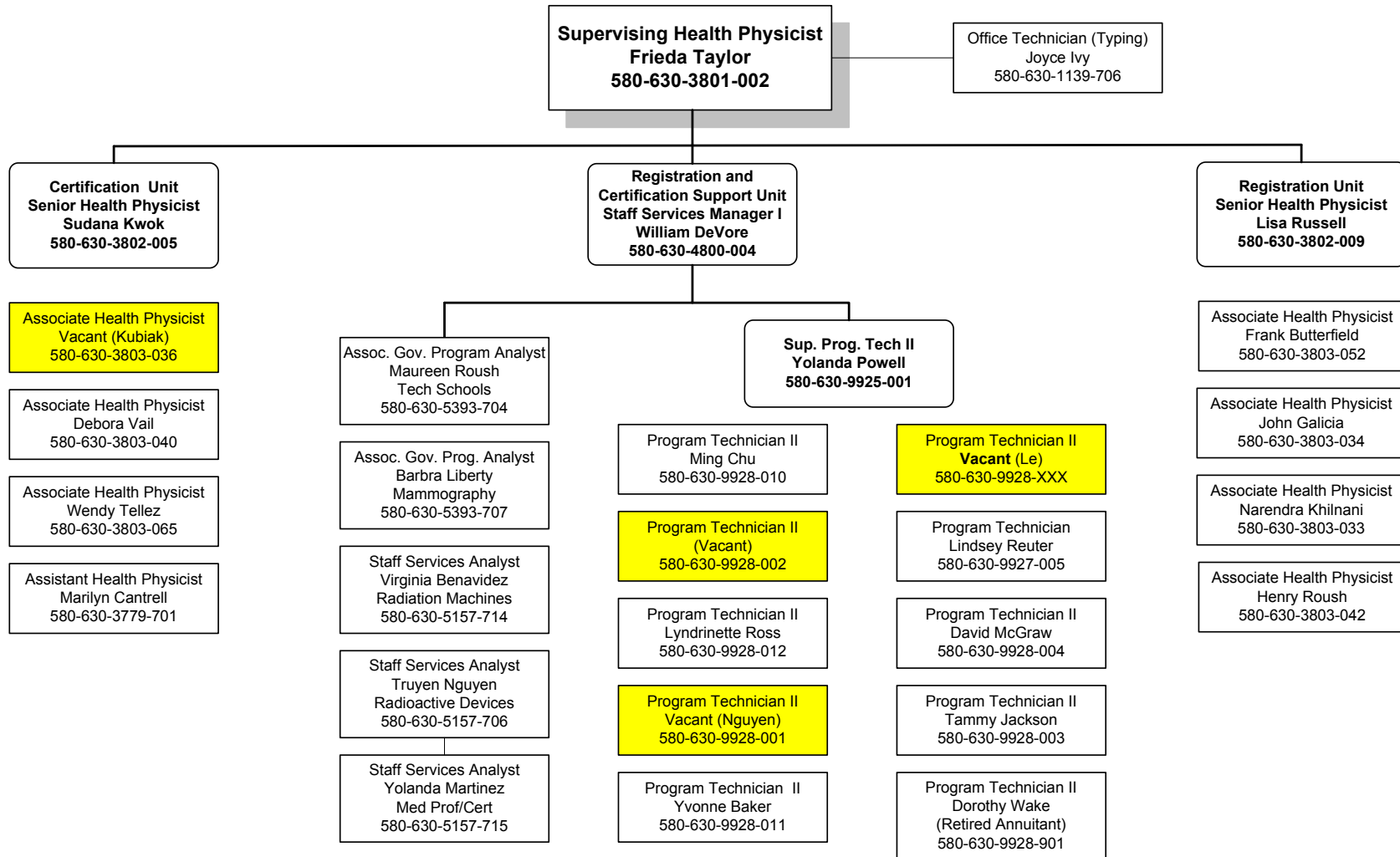
Associate Health Physicist
Jennifer Granger
580-630-3803-017

Assoc. Gov. Program Analyst
Judy Hardy
580-630-5393-711

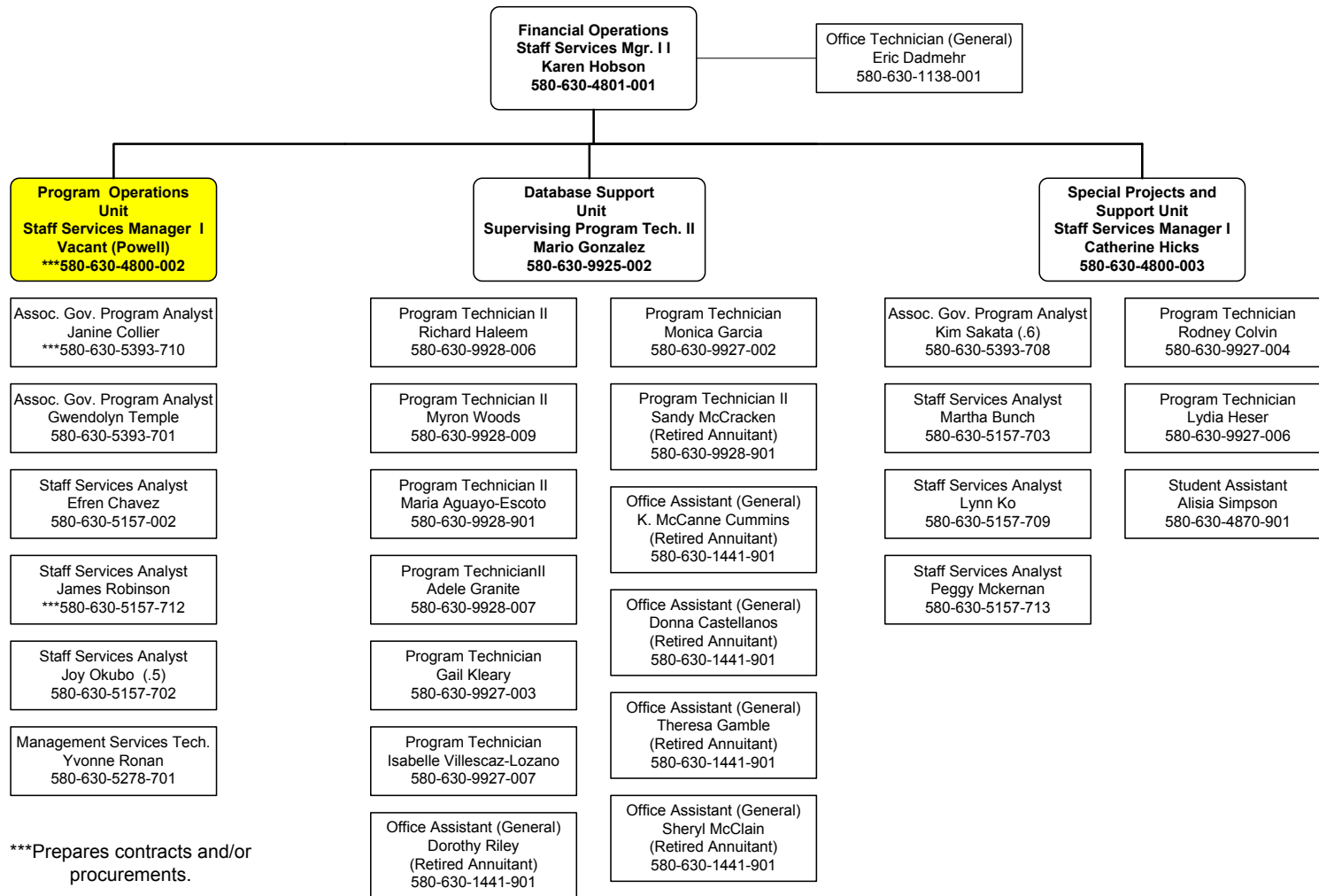
Associate Health Physicist
William Lorenzo
(Retired Annuitant)
580-630-3803-901

Assistant Health Physicist
(BCP PS-11 07/08)
Vacant
580-630-3779-XXX

Registration and Certification Section



Financial Operations and Analysis Section



APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1 Licensee: Radiation Oncology Services Inspection Type: Routine, Unannounced Inspection Date: 9/15/05	License No.: 5938 Priority: 2 Inspector: JH
File No.: 2 Licensee: South Coast Management District Inspection Type: Routine, Unannounced Inspection Date: 8/24/07	License No.: 1196 Priority: 5 Inspector: KH
File No.: 3 Licensee: Boeing Company Inspection Type: Routine, Unannounced Inspection Date: 7/9/07	License No.: 0015 Priority: 2 Inspector: DK
File No.: 4 Licensee: Northrup Grumman Inspection Type: Routine/Special, Announced Inspection Dates: 4/25/07	License No.: 0043 Priority: 2 Inspector: MG
File No.: 5 Licensee: Highland General Hospital Inspection Type: Routine, Unannounced Inspection Date: 4/26/07	License No.: 0175 Priority: 3 Inspector: MG
File No.: 6 Licensee: California Institute of Technology Inspection Type: Routine, Unannounced Inspection Date: 10/18/07	License No.: 0314 Priority: 2 Inspector: SD
File No.: 7 Licensee: California Surgery Center Inspection Type: Routine, Unannounced Inspection Date: 3/21/05	License No.: 6833 Priority: 3 Inspector: KF
File No.: 8 Licensee: Southern California Edison Inspection Type: Routine, Announced Inspection Dates: 3/5/08	License No.: 5244 Priority: 1 Inspector: DK

File No.: 9

Licensee: Certified Testing & Consulting Services
Inspection Type: Initial/Special, Announced
Inspection Date: 1/31/07

License No.: 3941
Priority: 1
Inspector: KF

File No.: 10

Licensee: Baker Atlas
Inspection Type: Initial/Special, Announced
Inspection Date: 2/25/08

License No.: 6284
Priority: 3
Inspector: DK

File No.: 11

Licensee: Arrow Inspection and Testing, Inc.
Inspection Type: Initial, Announced
Inspection Date: 1/25/08

License No.: 7600
Priority: 5
Inspector: AT

File No.: 12

Licensee: Ninyo & Moore Corporation
Inspection Type: Initial, Announced
Inspection Dates: 2/1/08

License No.: 7633
Priority: 5
Inspector: KH

File No.: 13

Licensee: Ohmart/Vega Corporation
Inspection Type: Reciprocity
Inspection Date: 9/11/07

License No.: OH 03214310002
Priority: N/A
Inspector: AT

File No.: 14

Licensee: GE Healthcare
Inspection Type: Reciprocity
Inspection Date: 12/12/07

License No.: WI 133-1107-01
Priority: N/A
Inspector: KH

File No.: 15

Licensee: Elekta, Inc.
Inspection Type: Reciprocity
Inspection Date: 8/30/07

License No.: GA 1153-1
Priority: N/A
Inspector: MG

File No.: 16

Licensee: Albany International
Inspection Type: Reciprocity
Inspection Dates: 2/13/07

License No.: NRC 39-32289-01
Priority: N/A
Inspector: JO

File No.: 17

Licensee: KMA Geoscience
Inspection Type: Routine, Unannounced
Inspection Date: 2/20/08

License No.: 6834
Priority: 5
Inspector: DA

File No.: 18

Licensee: Team Cooperhead – MQS Inc.
Inspection Type: Routine, Announced
Inspection Date: 4/3/07

License No.: 6720
Priority: 1
Inspector: KH

File No.: 19

Licensee: IESCO, Inc.
Inspection Type: Special/Follow up, Announced
Inspection Date: 2/5/08

License No.: 6571
Priority: 1
Inspector: DA

File No.: 20

Licensee: Tri Counties Blood Bank
Inspection Type: Initial/Special, Announced
Inspection Dates: 1/23/08

License No.: 5452
Priority: 5
Inspector: DK

File No.: 21

Licensee: Construction Materials Testing, Inc.
Inspection Type: Special/Followup, Unannounced
Inspection Dates: 12/6/07 and 1/2/08

License No.: 0799
Priority: 5
Inspector: KH

File No.: 22

Licensee: Testing Engineers, Inc.
Inspection Type: Routine, Announced
Inspection Date: 5/15/07

License No.: 3691
Priority: 5
Inspector: EM

File No.: 23

Licensee: Berthold Technologies USA, LLC.
Inspection Type: Reciprocity
Inspection Date: 6/12/07

License No.: TN R-01082-E12
Priority: N/A
Inspector: EM

File No.: 24

Licensee: Scripps Memorial Hospital
Inspection Type: Routine/Followup, Unannounced
Inspection Dates: 1/17-18/08

License No.: 1093
Priority: 2
Inspector: RY

File No.: 25

Licensee: Siemens Medical Solutions USA
Inspection Type: Routine, Unannounced
Inspection Date: 7/26/07

License No.: 0218
Priority: 5
Inspector: DA

File No.: 26

Licensee: University of California
Inspection Type: Initial/Special, Announced
Inspection Date: 4/10/07

License No.: 1335
Priority: 2
Inspectors: DK, KH

File No.: 27

Licensee: PharmaRx Pharmaceutical
Inspection Type: Routine, Unannounced
Inspection Date: 1/16/08

License No.: 7286
Priority: 2
Inspector: DK

File No.: 28

Licensee: Titan Systems Corporation
Inspection Type: Special, Announced
Inspection Dates: 6/12/07

License No.: 0553
Priority: 3
Inspector: EM

File No.: 29

Licensee: Synpep Corporation
Inspection Type: Decommissioning, Announced
Inspection Date: 1/11/07

License No.: 6137
Priority: N/A
Inspector: JW

File No.: 30

Licensee: ICN Biomedical
Inspection Type: Decommissioning, Announced
Inspection Date: 2/12/07

License No.: 17200
Priority: N/A
Inspector: KH

File No.: 31

Licensee: ABC Management, Inc.
Inspection Type: Decommissioning, Announced
Inspection Dates: 3/2/05, 5/18/05

License No.: 4755
Priority: 2
Inspector: HA

File No.: 32

Licensee: Philotechnics
Inspection Type: Reciprocity
Inspection Dates: 9/7/07

License No.: MA 56-0543
Priority: N/A
Inspector: SP

INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1

Licensee: Pacific Imaging
Inspection Type: Routine, Unannounced
Inspection Date: 1/28/08

License No.: 2252
Priority: 3
Inspector: KH

Accompaniment No.: 2

Licensee: City & County of San Francisco
Inspection Type: Routine, Unannounced
Inspection Date: 1/29/08

License No.: 3389
Priority: 5
Inspector: EM

Accompaniment No.: 3
Licensee: Vaca Valley Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 1/30/08

License No.: 4861
Priority: 3
Inspector: KF

Accompaniment No.: 4
Licensee: Eden Medical Center
Inspection Type: Routine, Unannounced
Inspection Date: 1/31/08

License No.: 1459
Priority: 3
Inspector: MG

Accompaniment No.: 5
Licensee: Kaiser Permanente Medical Center
Inspection Type: Routine, Announced
Inspection Date: 2/25/08

License No.: 2058
Priority: 3
Inspector: KH

Accompaniment No.: 6
Licensee: Ameron Steel Fabrication Division
Inspection Type: Special, Unannounced
Inspection Date: 2/26/08

License No.: 1004
Priority: 1
Inspector: AT

Accompaniment No.: 7
Licensee: Cardinal Health, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 2/27/08

License No.: 6925
Priority: 2
Inspector: SD

Accompaniment No.: 8
Licensee: Pacific Heart Institute
Inspection Type: Routine, Unannounced
Inspection Date: 2/28/08

License No.: 5414
Priority: 3
Inspector: JO

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1 Licensee: Subsurface Imaging, Inc. Type of Action: Amendment Date Issued: 3/18/08	License No.: 7449 Amendment No.: 13 License Reviewer: JR
File No.: 2 Licensee: Southern California Veterinary Imaging Type of Action: New Date Issued: 5/22/07	License No.: 7501 Amendment No.: N/A License Reviewer: FT
File No.: 3 Licensee: Cardinal Health Type of Action: Amendment Date Issued: 7/10/07	License No.: 3822 Amendment No.: 84 License Reviewer: CR
File No.: 4 Licensee: DIGIRAD Type of Action: Amendment Date Issued: 2/20/08	License No.: 5713 Amendment No.: 31 License Reviewer: PG
File No.: 5 Licensee: South Bay Inspection Services, Inc. Type of Action: New Date Issued: 1/19/07	License No.: 7525 Amendment No.: N/A License Reviewer: FT
File No.: 6 Licensee: Kaiser Permanente Medical Group Type of Action: Amendment Date Issued: 8/25/06	License No.: 1078 Amendment No.: 71 License Reviewer: TP
File No.: 7 Licensee: Hoag Memorial Hospital Presbyterian Type of Action: Amendment Dates Issued: 9/18/07, 3/27/08	License No.: 0272 Amendment Nos.: 100, 101 License Reviewer: TP
File No.: 8 Licensee: Regents of the University of California, San Francisco Type of Action: Amendment Dates Issued: 9/27/07, 11/9/07	License No.: 1725 Amendment Nos.: 93, 94 License Reviewer: BG

File No.: 9

Licensee: The Regents of the University of California, U.C. Davis

Type of Action: Denial (see comment)

Date Issued: Pending

License No.: 1334

Amendment No.: N/A

License Reviewer: HWA

Comment:

The amendment is being held pending satisfactory resolution of a Form 5010 issue.

File No.: 10

Licensee: Well Analysis Corporation, Inc.

Type of Action: Amendment

Date Issued: 1/31/08

License No.: 4210

Amendment No.: 26

License Reviewer: PG

File No.: 11

Licensee: Arminius Corporation

Type of Action: New

Date Issued: 1/17/08

License No.: 7662

Amendment No.: N/A

License Reviewers: PG, JR

File No.: 12

Licensee: Pregis Protective Packaging, Inc.

Type of Action: Termination

Date Issued: 10/25/07

License No.: 6185

Amendment No.: 7

License Reviewer: MG

File No.: 13

Licensee: B&B Environmental Safety

Type of Action: Amendment

Date Issued: 2/27/08

License No.: 7540

Amendment No.: 2

License Reviewer: JF

File No.: 14

Licensee: The J. Byer Group, Inc.

Type of Action: Renewal

Date Issued: 3/15/07

License No.: 6094

Amendment No.: 7

License Reviewer: BH

File No.: 15

Licensee: Shaw Environmental

Type of Action: New

Date Issued: 3/25/08

License No.: 7704

Amendment No.: N/A

License Reviewer: BB

File No.: 16

Licensee: Dynamic Geo Testing

Type of Action: New

Date Issued: 3/5/08

License No.: 7687

Amendment No.: N/A

License Reviewer: ZG

File No.: 17

Licensee: Advanced Cell Technology

Type of Action: New

Date Issued: 1/16/07

License No.: 7588

Amendment No.: N/A

License Reviewer: JR

File No.: 18

Licensee: The Aerospace Corporation
Type of Action: Amendment
Date Issued: 10/5/07

License No.: 0305
Amendment No.: 77
License Reviewer: LL

File No.: 19

Licensee: Rad Net Management
Type of Action: New
Date Issued: 11/3/04

License No.: 7373
Amendment No.: N/A
License Reviewer: MS

File No.: 20

Licensee: Foothill Cardiology CA Heart Medical Group
Type of Action: Amendment
Date Issued: 11/21/07

License No.: 7622
Amendment No.: 1
License Reviewer: PL

File No.: 21

Licensee: Kaiser Permanente
Type of Action: Renewal
Date Issued: 8/24/07

License No.: 6082
Amendment No.: 15
License Reviewer: SP

File No.: 22

Licensee: Yolo County Planning, Resources
and Public Works Department
Type of Action: Renewal
Date Issued: 1/3/08

License No.: 1742
Amendment No.: 18
License Reviewer: FM

File No.: 23

Licensee: Phoenix Pharmaceuticals Inc.
Type of Action: Renewal
Date Issued: 11/7/07

License No.: 6172
Amendment No.: 10
License Reviewer: DCT

File No.: 24

Licensee: Synpep Corporation
Type of Action: Termination
Date Issued: 4/25/07

License No.: 6137
Amendment No.: 9
License Reviewer: LL

File No.: 25

Licensee: Univ. CA Irvine Medical Center
Type of Action: Amendment
Date Issued: 1/29/08

License No.: 0278
Amendment No.: 163
License Reviewer: HA

File No.: 26

Licensee: ABC Management, Inc.
Type of Action: Termination
Date Issued: 6/1/07

License No.: 4755
Amendment No.: 30
License Reviewer: HA

File No.: 27
Licensee: ICN Biomedicals
Type of Action: Termination
Date Issued: 12/7/07

License No.: 7200
Amendment No.: 8
License Reviewer: FM

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1

Licensee: Pomona Valley Hospital

Date of Incident: 5/24/06

Investigation Date: 5/26/06

License No.: 0764

NMED Log No.: 060399

Type of Incident: Lost/Stolen Material

Type of Investigation: Site

File No.: 2

Licensee: North Oaks Radiation Center

Date of Incident: 8/9/06

Investigation Date: 8/14/06

License No.: 3693

NMED Log No.: 060515

Type of Incident: Medical

Type of Investigation: Telephone

Comment:

The Branch did not report event to NRC Headquarters Operations Center within required 24 hours.

File No.: 3

Licensee: Adams Steel

Date of Incident: 8/29/06

Investigation Date: 8/30/06

License No.: N/A

NMED Log No.: 060555

Type of Incident: Lost/Stolen Material

Type of Investigation: Site

File No.: 4

Licensee: Schlumberger Technology

Date of Incident: 10/4/06

Investigation Date: 10/7/06

License No.: 0144

NMED Log No.: 060633

Type of Incident: Contamination/Leaking Source

Type of Investigation: Site

File No.: 5

Licensee: California State Polytechnic University

Date of Incident: 10/06

Investigation Date: 12/6/06

License No.: 0496

NMED Log No.: 060752

Type of Incident: Lost/Stolen Material

Type of Investigation: Site

File No.: 6

Licensee: Smith-Emery Co.

Date of Incident: 3/2/07

Investigation Date: 3/2/07

License No.: 2878

NMED Log No.: 070133

Type of Incident: Damaged Equipment

Type of Investigation: Telephone

File No.: 7

Licensee: Leland Stanford, Jr., University
Date of Incident: 3/5-9/07
Investigation Date: 3/14/07

License No.: 0676
NMED Log No.: 070216
Type of Incident: Lost/Stolen Material
Type of Investigation: Site

Comment:

The Branch reported the event under 10 CFR 2202 as a 30-day reportable event; however, the event should have been reported under 10 CFR 2201 within 24 hours of notification from the licensee.

File No.: 8

Licensee: Ravi Patel, M.D.
dba California Surgery Center
Date of Incident: 3/19/07
Investigation Date: 4/6/07

License No.: 6833
NMED Log No.: 070180
Type of Incident: Medical
Type of Investigation: Telephone

File No.: 9

Licensee: Good Samaritan Hospital
Date of Incident: 8/14/06
Investigation Date: 8/16/06

License No.: 1731
NMED Log No.: 060527
Type of Incident: Equipment Failure
Type of Investigation: Site

Comment:

The Branch did not report event to NRC Headquarters Operations Center in a timely manner.

File No.: 10

Licensee: Cedars Sinai Medical Center
Date of Incident: 1/17/07
Investigation Date: 1/18/07

License No.: 0404
NMED Log No.: 070089
Type of Incident: Loss of Control
Type of Investigation: Site

File No.: 11

Licensee: Converse Consultants
Date of Incident: 5/22/07
Investigation Date: 5/22/07

License No.: 4057
NMED Log No.: 070316
Type of Incident: Lost/Stolen Material
Type of Investigation: Site

File No.: 12

Licensee: Chapman Medical Center, Inc.
Date of Incident: 10/10/06
Investigation Date: 10/10/06

License No.: 1946
NMED Log No.: 060634
Type of Incident: Lost/Stolen Material
Type of Investigation: Site

File No.: 13
Licensee: Taormina (CVT)
Date of Incident: 6/1/07
Investigation Dates: 6/1 and 4/07

License No.: N/A
NMED Log No.: 070316
Type of Incident: Landfill Alarm
Type of Investigation: Site

File No.: 14
Licensee: Geomat Testing Laboratories
Date of Incident: 10/15/07
Investigation Date: 10/22/07

License No.: 5735
NMED Log No.: 070655
Type of Incident: Lost/Stolen Material
Type of Investigation: Licensee Report

File No.: 15
Licensee: Kaiser Permanente
Date of Incident: 5/16/07
Investigation Date: N/A

License No.: 2072
NMED Log No.: 070512
Type of Incident: Lost/Stolen Material
Type of Investigation: Site

SEALED SOURCE AND DEVICE INCIDENT CASEWORKS REVIEWS

File No.: 1
Licensee: University of California, Irvine
Date of Incident: 2/17/05
Investigation Date: 2/24/05

License No.: 1338
Incident Log No.: Book 2/#1
Type of Incident: Leaking source
Type of Investigation: Technical review

Comment:

The close-out information was entered and dated, but not signed or initialed.

File No.: 2
Licensee: Isotope Product Laboratories
Date of Incident: 12/9/05
Investigation Date: 12/12/05

License No.: 1509
Incident Log No.: Book 2/#2
Type of Incident: (False) Containment crack
Type of Investigation: Telephone

File No.: 3
Licensee: Varian
Date of Incident: 8/12/04
Investigation Date: 8/27/04

License No.: 3092
Incident Log No.: Book 2/#3
Type of Incident: Leaking source
Type of Investigation: Technical review

Comment:

The close-out information was entered, dated, but not signed or initialed.

File No.: 4
Licensee: Raytheon Co.
Date of Incident: 8/2/04
Investigation Date: 10/28/04

License No.: 1053
Incident Log No.: Book 2/#4
Type of Incident: Interlock failure
Type of Investigation: Technical review

File No.: 5
Licensee: Ancore Corp.
Date of Incident: 12/23/03
Investigation Date: 10/13/04

License No.: 2484
Incident Log No.: Book 2/#5
Type of Incident: Equipment malfunction
Type of Investigation: Amendment of SS&D registration

Comments:

- a) The equipment was used outside specifications; SS&D registration certificate CA-0598-D-115-S was amended for environmental conditions to include outdoors use.
- b) Proprietary information was not marked in accordance with the Branch's procedure.

File No.: 6
Licensee: University of California, Los Angeles
Date of Incident: 1/26/06
Investigation Date: 1/27/06

License No.: 1335
Incident Log No.: Book 2/#6
Type of Incident: Leaking source
Type of Investigation: Forwarded to New York State

Comment:

Close-out information was entered, dated, but not signed or initialed.

File No.: 7
Licensee: HCA/Good Samaritan Hospital
Date of Incident: 8/16/06
Investigation Date: 1/4/07

License No.: 1731
Incident Log No.: Book 2/#7
Type of Incident: Stuck source
Type of Investigation: Technical review

File No.: 8
Licensee: Decisive Testing Co.
Date of Incident: 3/5/04
Investigation Date: 3/11/04

License No.: 1836
Incident Log No.: Book 2/#8
Type of Incident: Source disconnect
Type of Investigation: Inspection

File No.: 9
Licensee: City of Hope/Beckman Research Institute
Date of Incident: 7/16/07
Investigation Date: 12/27/07

License No.: 0307
Incident Log No.: Book 2/#9
Type of Incident: HDR malfunction
Type of Investigation: Inspection

File No.: 10

Licensee: University of California, Irvine
Date of Incident: 6/24/04
Investigation Dates: 7/9/04-4/26/05

License No.: FL-2816-1
Incident Log Nos.: FL03-192; NMED 030847
Type of Incident: Leaking source
Type of Investigation: Inspection

File No.: 11

Licensee: Isotope Product Laboratories
Date of Incident: 9/3/04
Investigation Date: 3/13/06

License No.: 1509
Incident Log No.: Book 3/#2
Type of Incident: Leaking source
Type of Investigation: Amendment of SS&D registration

File No.: 12

Licensee: Isotope Product Laboratories
Date of Incident: 10/19/04
Investigation Date: 3/14/06

License No.: 1509
Incident Log No.: Book 3/#3
Type of Incident: Leaking source
Type of Investigation: Technical review

File No.: 13

Licensee: Beckman Coulter, Inc.
Date of Incident: 12/27/04
Investigation Date: 5/11/06

License No.: 0441
Incident Log No.: Book 3/#4
Type of Incident: Leaking source
Type of Investigation: Inspection

No.: 14

Licensee: Sabia
Date of Incident: 1/11/06
Investigation Date: 3/24/07

License No.: 6663
Incident Log No.: Book 3/#8
Type of Incident: Equipment malfunction
Type of Investigation: Referred case to NRC

File No.: 15

Licensee: Schlumberger, Inc.
Date of Incident: 10/6/06
Investigation Date: 10/12/06

License No.: 0144
Incident Log No.: Book 4/#3
Type of Incident: Source rupture
Type of Investigation: License amendment

File No.: 16

Licensee: Beckman Coulter, Inc.
Date of Incident: 9/17/07
Investigation Date: 3/21/08

License No.: FL-2816-1
Incident Log Nos.: FL03-192; NMED 030847
Type of Incident: Lost/Stolen RAM
Type of Investigation: Amendment of SS&D registration

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

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

File No.: 1

Registry No.: CA-8169-S-801-S

Applicant Name: Radiance Medical Systems, Inc.

Date Issued: 7/11/07

SS&D Type: (V) General Medical Use

Type of Action: Inactivation

SS&D Reviewers: RR, JF

Comment:

The folder contained the original application and subsequent documents, but the inactivated registration certificate was not in the records. The inactivated registration certificate was available in the National Registry on the internet.

File No.: 2

Registry No.: CA-0305-D-102-S

Applicant Name: Thermo Gamma Matrix, Inc.

Date Issued: 8/17/07

SS&D Type: (H) General Neutron Source

Type of Action: Amendment

SS&D Reviewers: ZG, RR

File No.: 3

Registry No.: CA-0309-D-103-G

Applicant Name: General Atomics

Date Issued: 11/6/07

SS&D Type: (D) Gamma Gauge

Type of Action: New Registration

SS&D Reviewers: RR, JF

Comment:

Isotope activity was unconventionally listed on the first page as a nominal value with tolerances (i.e. 0.05 uCi +/-10%).

File No.: 4

Registry No.: CA-0406-S-228-S

Applicant Name: Eckert & Ziegler Isotope Products

Date Issued: 12/5/07

SS&D Type: (F) Well-logging Source

Type of Action: Amendment

SS&D Reviewers: FM, HA

Comments:

- a) The amended text was not shown in bold, which is the conventional method to show changes.
- b) Isotope activity was unconventionally listed on the first page as a nominal value. In the Description section, the activity was shown with tolerances.

File No.: 5

Registry No.: CA-0215-D-102-B

Applicant Name: Science Applications, Inc.

Date Issued: 1/10/08

SS&D Type: (D) Gamma Gauge

Type of Action: Amendment

SS&D Reviewers: ZG, JF

Comments:

- a) Isotope activity was unconventionally listed on the first page as a nominal value with tolerances.
- b) Description (Page 3, Paragraph 3) did not show the change in the Amendment from the previous edition (i.e., the divergence was changed from 5° to 3 – 5°).
- c) Attachment 5, "Typical Labels...", has not been updated; it still showed the labels from the previous edition.
- d) Attachments 7 and 8 did not show changes in bold.

File No.: 6

Registry No.: CA-0305-D-109-S

Applicant Name: Thermo Gamma Matrix, Inc.

Date Issued: 10/22/07

SS&D Type: (H) General Neutron Source

Type of Action: Amendment

SS&D Reviewers: MG, JF

Comment:

In the amendment, a new source was added; however, the records did not show that a technical evaluation was conducted regarding the equivalency of the new source to those that had been included in the previous edition.

File No.: 7

Registry No.: CA-0406-S-214-S

Applicant Name: Eckert & Ziegler Isotope Products

Date Issued: 1/31/08

SS&D Type: (S) Foil Source

Type of Action: Amendment

SS&D Reviewers: FM, JF

Comment:

Proprietary information was not marked in accordance with the Branch's procedure.

File No.: 8

Registry No.: CA-0408-S-221-S

Applicant Name: Eckert & Ziegler Isotope Products

Date Issued: 7/27/04

SS&D Type: (U) X-ray Fluorescence

Type of Action: New Registration

SS&D Reviewers: HA, JF

File No.: 9

Registry No.: CA-0598-D-115-S

Applicant Name: J. L. Shepherd and Associates

Date Issued: 8/20/04

SS&D Type: (K) Gamma Irradiator

Type of Action: Amendment

SS&D Reviewers: JF, HA

File No.: 10

Registry No.: CA-0380-D-101-S

Applicant Name: Nova R&D, Inc.

Date Issued: 9/4/04

SS&D Type: (H) General Neutron Source

Type of Action: Amendment

SS&D Reviewers: FM, JF

File No.: 11

Registry No.: CA-0102-D104-S

Applicant Name: ADAC Laboratories, Inc.

Date Issued: 11/24/04

SS&D Type: (Y) Calibration

Type of Action: Amendment

SS&D Reviewers: SK, JF

Comments:

- a) Isotope activity was unconventionally listed on the first page as a nominal value with tolerances.
- b) Proprietary information was not marked in accordance with the Branch's procedure.

File No.: 12

Registry No.: CA-0102-D-105-S

Applicant Name: ADAC Laboratories, Inc.

Date Issued: 12/22/04

SS&D Type: (Y) Calibrator

Type of Action: New Registration

SS&D Reviewers: JF, HA

Comments:

- a) The quality assurance measures for the U.S. distributor of a product manufactured overseas were not reviewed in accordance with the guidance in Section 10.7, NUREG-1556, Vol. 3, Rev. 1.
- b) Isotope activity was unconventionally listed on the first page as a nominal value with tolerances.

File No.: 13

Registry No.: CA-1213-S-102-S

Applicant Name: Belden Engineering

Date Issued: 4/7/05

SS&D Type: (D) Gamma Gauge

Type of Action: New Registration

SS&D Reviewers: MG, JF

Comment:

The quality assurance measures for the U.S. distributor of a product manufactured overseas were not reviewed in accordance with the guidance in Section 10.7, NUREG-1556, Vol. 3, Rev. 1.

File No.: 14

Registry No.: CA-1213-D-101-B

Applicant Name: Belden Engineering

Date Issued: 4/11/05

SS&D Type: (D) Gamma Gauge

Type of Action: New Registration

SS&D Reviewers: NG, JF

Comment:

The quality assurance measures for the U.S. distributor of a product manufactured overseas were not reviewed in accordance with the guidance in Section 10.7, NUREG-1556, Vol. 3, Rev. 1.

File No.: 15

Registry No.: CA-0406-S-238-S

Applicant Name: Eckert & Ziegler Isotope Products

Date Issued: 7/11/07

SS&D Type: (X) Medical Reference Source

Type of Action: New Registration

SS&D Reviewers: FM, HA

File No.: 16

Registry No.: CA-1046-D-102-S

Applicant Name: Analyser Systems, Inc.

Date Issued: 2/28/06

SS&D Type: (H) General Neutron Source

Type of Action: New Registration

SS&D Reviewers: NG, JF

Comment:

Isotope activity was unconventionally listed on the first page as a nominal value with tolerances.

File No.: 17

Registry No.: CA-0305-D-111-S

Applicant Name: Thermo Electron Corp.

Date Issued: 5/3/06

SS&D Type: (U) X-Ray Fluorescence

Type of Action: New Registration

SS&D Reviewers: DCT, JF

Comments:

- a) The quality assurance measures for the U.S. distributor of a product manufactured overseas were requested in accordance with the guidance in Section 10.7, NUREG-1556, Vol. 3, Rev. 1; however, the Branch accepted an incomplete response.
- b) Proprietary information was not marked in accordance with the Branch's procedure.

File No.: 18

Registry No.: CA-0598-D-113-S

Applicant Name: J. L. Shepherd and Associates

Date Issued: 5/25/06

SS&D Type: (J) Gamma Irradiator

Type of Action: Amendment

SS&D Reviewers: NG, JF

File No.: 19

Registry No.: CA-0406-D-107-S

Applicant Name: Isotope Product Labs.

Date Issued: 7/14/06

SS&D Type: (X) Medical Reference Source

Type of Action: Amendment

SS&D Reviewers: BB, JF

File No.: 20

Registry No.: CA-1259-D-101-S

Applicant Name: HiEnergy Technologies, Inc.

Date Issued: 9/29/06

SS&D Type: (H) General Neutron Source

Type of Action: New Registration

SS&D Reviewers: RR, JF

Comment:

Proprietary information was not marked in accordance with the Branch's procedure.

File No.: 21

Registry No.: CA-0510-D-130-S

Applicant Name: North American Scientific

Date Issued: 7/2/07

SS&D Type: (AA) Manual Brachytherapy

Type of Action: New Registration

SS&D Reviewers: FM, JF

File No.: 22

Registry No.: CA-0305-D-105-S

Applicant Name: Thermo Gamma Metrix, Inc.

Date Issued: 6/27/07

SS&D Type: (H) General Neutron Source

Type of Action: Amendment

SS&D Reviewers: ZG, JF

Comment:

Proprietary information was not marked in accordance with the Branch's procedure.

ATTACHMENT

May 29, 2008, Letter from Gary W. Butner
California's Response to Draft IMPEP Report

ADAMS ACCESSION NO.: ML081630647



MARK B HORTON, MD, MSPH
Director

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



ARNOLD SCHWARZENEGGER
Governor

May 29, 2008

Mr. Dennis M. Sollenberger
Office of Federal and State Materials
And Environmental Management Programs
USNRC Mailstop T-8-E24
Washington, DC 20555

Dear Mr. Sollenberger:

The California Department of Public Health (CDPH) has reviewed the Integrated Materials Performance Evaluation Program (IMPEP) draft report dated May 1, 2008. We would like to thank you and the entire IMPEP team for your comprehensive review of our Agreement State programs.

CDPH is committed to conducting a quality Radiation Safety program, which complies with all the Nuclear Regulatory Commission (NRC) requirements and also protects public health safety. Please find enclosed 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.

Sincerely,

Gary W. Butner
Acting Branch Chief
Radiologic Health Branch

Enclosure

cc: See next page

Mr. Dennis M. Sollenberger
Page 2
May 29, 2008

cc: Tony Agurto
Assistant Division Chief
Division of Food, Drug and Radiation Safety

Rufus B. Howell
Acting Deputy Director
Center for Environmental Health

Robert Schlag
Assistant Deputy Director
Center for Environmental Health

Cover Letter

Page 1, paragraph 1: We realize that standard boiler plate language was used in the last sentence, but in order to minimize the potential for misinterpretation by California readers of the IMPEP report outside of the Radiologic Health Branch, we believe there should be a clearer association between "not compatible" and our problems in enacting regulations. We believe this can be accomplished by changing the last word in this sentence from "program" to "regulations." Also, you may want to begin the last phrase of the last sentence with ", but" instead of with "and."

Technical Staffing and Training

Page 4, paragraph 3: "Physicists" should be "Physicist" on the 8th line.

Status of Materials Inspection Program

Page 5, paragraph 4: We believe the following two sentences should be inserted following the 2nd sentence "The HDR priority change was made in 1998 based on an evaluation of safety findings during inspections of these licensees. The 1999 IMPEP evaluation found this to be a "Good Practice," and the 2004 IMPEP evaluation did not comment negatively on the Branch's continued HDR prioritization as Priority 3." We believe this change will put into better perspective the Branch's good intentions with respect to the prioritization of HDRs

The recommendation in the last sentence of this paragraph recommends "the State review the inspection priority of each license type to ensure they are, at least, consistent with the priority established in IMC 2800", this language is confusing in light of the first sentence of this same paragraph.

Technical Quality of Incident and Allegation Activities

Page 10, paragraph 3: This paragraph doesn't accurately reflect how we report events to NRC. We report only 24-hour events to HOO, either by phone, fax, or email. We may or may not use our 5010 form in reporting the 24-hr events to HOO. All events are reported to NMED (via INL), including those reported to HOO. We always submit our 5010 form to NMED (INL).

Attachment to Response to Draft IMPEP Report
May 29, 2008
Page 4

Page 10, paragraph 4: We believe the 4th sentence in this paragraph should be changed to read "The Branch was unaware of one of the allegations, and had not entered the other into their 5010 system at the time of the IMPEP even though it should have been entered into their 5010 system approximately one month earlier by their procedures. Contributing to these problems was a change in addressees used by NRC when forwarding allegations to the Branch."

Summary

Page 18, last paragraph – item 1: Same comment as stated above in Status of Materials Inspection Program, 2nd paragraph.