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 18, 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

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Enclosure:
California Final IMPEP Report
cc w/enclosure: See next page.
Distribution : See next page.

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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 allegers' 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 comprised. (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

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

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APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: Radiation Oncology Services — License No.: 5938
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 9/15/05 — Inspector: JH

File No.: 2
Licensee: South Coast Management District — License No.: 1196
Inspection Type: Routine, Unannounced — Priority: 5
Inspection Date: 8/24/07 — Inspector: KH

File No.: 3
Licensee: Boeing Company — License No.: 0015
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 7/9/07 — Inspector: DK

File No.: 4
Licensee: Northrup Grumman — License No.: 0043
Inspection Type: Routine/Special, Announced — Priority: 2
Inspection Dates: 4/25/07 — Inspector: MG

File No.: 5
Licensee: Highland General Hospital — License No.: 0175
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 4/26/07 — Inspector: MG

File No.: 6
Licensee: California Institute of Technology — License No.: 0314
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 10/18/07 — Inspector: SD

File No.: 7
Licensee: California Surgery Center — License No.: 6833
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 3/21/05 — Inspector: KF

File No.: 8
Licensee: Southern California Edison — License No.: 5244
Inspection Type: Routine, Announced — Priority: 1
Inspection Dates: 3/5/08 — Inspector: DK

File No.: 9
Licensee: Certified Testing & Consulting Services
License No.: 3941
Inspection Type: Initial/Special, Announced
Priority: 1
Inspection Date: 1/31/07
Inspector: KF

File No.: 10
Licensee: Baker Atlas
License No.: 6284
Inspection Type: Initial/Special, Announced
Priority: 3
Inspection Date: 2/25/08
Inspector: DK

File No.: 11
Licensee: Arrow Inspection and Testing, Inc.
License No.: 7600
Inspection Type: Initial, Announced
Priority: 5
Inspection Date: 1/25/08
Inspector: AT

File No.: 12
Licensee: Ninyo & Moore Corporation
License No.: 7633
Inspection Type: Initial, Announced
Priority: 5
Inspection Dates: 2/1/08
Inspector: KH

File No.: 13
Licensee: Ohmart/Vega Corporation
License No.: OH 03214310002
Inspection Type: Reciprocity
Priority: N/A
Inspection Date: 9/11/07
Inspector: AT

File No.: 14
Licensee: GE Healthcare
License No.: WI 133-1107-01
Inspection Type: Reciprocity
Priority: N/A
Inspection Date: 12/12/07
Inspector: KH

File No.: 15
Licensee: Elekta, Inc.
License No.: GA 1153-1
Inspection Type: Reciprocity
Priority: N/A
Inspection Date: 8/30/07
Inspector: MG

File No.: 16
Licensee: Albany International
License No.: NRC 39-32289-01
Inspection Type: Reciprocity
Priority: N/A
Inspection Dates: 2/13/07
Inspector: JO

File No.: 17
Licensee: KMA Geoscience
License No.: 6834
Inspection Type: Routine, Unannounced
Priority: 5
Inspection Date: 2/20/08
Inspector: DA

File No.: 18
Licensee: Team Cooperhead – MQS Inc. License No.: 6720
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 4/3/07 Inspector: KH

File No.: 19
Licensee: IESCO, Inc. License No.: 6571
Inspection Type: Special/Follow up, Announced Priority: 1
Inspection Date: 2/5/08 Inspector: DA

File No.: 20
Licensee: Tri Counties Blood Bank License No.: 5452
Inspection Type: Initial/Special, Announced Priority: 5
Inspection Dates: 1/23/08 Inspector: DK

File No.: 21
Licensee: Construction Materials Testing, Inc. License No.: 0799
Inspection Type: Special/Followup, Unannounced Priority: 5
Inspection Dates: 12/6/07 and 1/2/08 Inspector: KH

File No.: 22
Licensee: Testing Engineers, Inc. License No.: 3691
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 5/15/07 Inspector: EM

File No.: 23
Licensee: Berthold Technologies USA, LLC. License No.: TN R-01082-E12
Inspection Type: Reciprocity Priority: N/A
Inspection Date: 6/12/07 Inspector: EM

File No.: 24
Licensee: Scripps Memorial Hospital License No.: 1093
Inspection Type: Routine/Followup, Unannounced Priority: 2
Inspection Dates: 1/17-18/08 Inspector: RY

File No.: 25
Licensee: Siemens Medical Solutions USA License No.: 0218
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 7/26/07 Inspector: DA

File No.: 26
Licensee: University of California License No.: 1335
Inspection Type: Initial/Special, Announced Priority: 2
Inspection Date: 4/10/07 Inspectors: DK, KH

File No.: 27
Licensee: PharmaRx Pharmaceutical License No.: 7286
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 1/16/08 Inspector: DK

File No.: 28
Licensee: Titan Systems Corporation License No.: 0553
Inspection Type: Special, Announced Priority: 3
Inspection Dates: 6/12/07 Inspector: EM

File No.: 29
Licensee: Synpep Corporation License No.: 6137
Inspection Type: Decommissioning, Announced Priority: N/A
Inspection Date: 1/11/07 Inspector: JW

File No.: 30
Licensee: ICN Biomedical License No.: 17200
Inspection Type: Decommissioning, Announced Priority: N/A
Inspection Date: 2/12/07 Inspector: KH

File No.: 31
Licensee: ABC Management, Inc. License No.: 4755
Inspection Type: Decommissioning, Announced Priority: 2
Inspection Dates: 3/2/05, 5/18/05 Inspector: HA

File No.: 32
Licensee: Philotechnics License No.: MA 56-0543
Inspection Type: Reciprocity Priority: N/A
Inspection Dates: 9/7/07 Inspector: SP

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Pacific Imaging License No.: 2252
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 1/28/08 Inspector: KH

Accompaniment No.: 2
Licensee: City & County of San Francisco License No.: 3389
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 1/29/08 Inspector: EM

Accompaniment No.: 3
Licensee: Vaca Valley Hospital — License No.: 4861
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 1/30/08 — Inspector: KF

Accompaniment No.: 4
Licensee: Eden Medical Center — License No.: 1459
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 1/31/08 — Inspector: MG

Accompaniment No.: 5
Licensee: Kaiser Permanente Medical Center — License No.: 2058
Inspection Type: Routine, Announced — Priority: 3
Inspection Date: 2/25/08 — Inspector: KH

Accompaniment No.: 6
Licensee: Ameron Steel Fabrication Division — License No.: 1004
Inspection Type: Special, Unannounced — Priority: 1
Inspection Date: 2/26/08 — Inspector: AT

Accompaniment No.: 7
Licensee: Cardinal Health, Inc. — License No.: 6925
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 2/27/08 — Inspector: SD

Accompaniment No.: 8
Licensee: Pacific Heart Institute — License No.: 5414
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 2/28/08 — Inspector: JO

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Subsurface Imaging, Inc. License No.: 7449
Type of Action: Amendment Amendment No.: 13
Date Issued: 3/18/08 License Reviewer: JR

File No.: 2
Licensee: Southern California Veterinary Imaging License No.: 7501
Type of Action: New Amendment No.: N/A
Date Issued: 5/22/07 License Reviewer: FT

File No.: 3
Licensee: Cardinal Health License No.: 3822
Type of Action: Amendment Amendment No.: 84
Date Issued: 7/10/07 License Reviewer: CR

File No.: 4
Licensee: DIGIRAD License No.: 5713
Type of Action: Amendment Amendment No.: 31
Date Issued: 2/20/08 License Reviewer: PG

File No.: 5
Licensee: South Bay Inspection Services, Inc. License No.: 7525
Type of Action: New Amendment No.: N/A
Date Issued: 1/19/07 License Reviewer: FT

File No.: 6
Licensee: Kaiser Permanente Medical Group License No.: 1078
Type of Action: Amendment Amendment No.: 71
Date Issued: 8/25/06 License Reviewer: TP

File No.: 7
Licensee: Hoag Memorial Hospital Presbyterian License No.: 0272
Type of Action: Amendment Amendment Nos.: 100, 101
Dates Issued: 9/18/07, 3/27/08 License Reviewer: TP

File No.: 8
Licensee: Regents of the University of California, San Francisco License No.: 1725
Type of Action: Amendment Amendment Nos.: 93, 94
Dates Issued: 9/27/07, 11/9/07 License Reviewer: BG

File No.: 9
Licensee: The Regents of the University of California, U.C. Davis License No.: 1334
Type of Action: Denial (see comment) Amendment No.: N/A
Date Issued: Pending 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. License No.: 4210
Type of Action: Amendment Amendment No.: 26
Date Issued: 1/31/08 License Reviewer: PG

File No.: 11
Licensee: Arminius Corporation License No.: 7662
Type of Action: New Amendment No.: N/A
Date Issued: 1/17/08 License Reviewers: PG, JR

File No.: 12
Licensee: Pregis Protective Packaging, Inc. License No.: 6185
Type of Action: Termination Amendment No.: 7
Date Issued: 10/25/07 License Reviewer: MG

File No.: 13
Licensee: B&B Environmental Safety License No.: 7540
Type of Action: Amendment Amendment No.: 2
Date Issued: 2/27/08 License Reviewer: JF

File No.: 14
Licensee: The J. Byer Group, Inc. License No.: 6094
Type of Action: Renewal Amendment No.: 7
Date Issued: 3/15/07 License Reviewer: BH

File No.: 15
Licensee: Shaw Environmental License No.: 7704
Type of Action: New Amendment No.: N/A
Date Issued: 3/25/08 License Reviewer: BB

File No.: 16
Licensee: Dynamic Geo Testing License No.: 7687
Type of Action: New Amendment No.: N/A
Date Issued: 3/5/08 License Reviewer: ZG

File No.: 17
Licensee: Advanced Cell Technology License No.: 7588
Type of Action: New Amendment No.: N/A
Date Issued: 1/16/07 License Reviewer: JR

File No.: 18
Licensee: The Aerospace Corporation — License No.: 0305
Type of Action: Amendment — Amendment No.: 77
Date Issued: 10/5/07 — License Reviewer: LL

File No.: 19
Licensee: Rad Net Management — License No.: 7373
Type of Action: New — Amendment No.: N/A
Date Issued: 11/3/04 — License Reviewer: MS

File No.: 20
Licensee: Foothill Cardiology CA Heart Medical Group — License No.: 7622
Type of Action: Amendment — Amendment No.: 1
Date Issued: 11/21/07 — License Reviewer: PL

File No.: 21
Licensee: Kaiser Permanente — License No.: 6082
Type of Action: Renewal — Amendment No.: 15
Date Issued: 8/24/07 — License Reviewer: SP

File No.: 22
Licensee: Yolo County Planning, Resources and Public Works Department — License No.: 1742
Type of Action: Renewal — Amendment No.: 18
Date Issued: 1/3/08 — License Reviewer: FM

File No.: 23
Licensee: Phoenix Pharmaceuticals Inc. — License No.: 6172
Type of Action: Renewal — Amendment No.: 10
Date Issued: 11/7/07 — License Reviewer: DCT

File No.: 24
Licensee: Synpep Corporation — License No.: 6137
Type of Action: Termination — Amendment No.: 9
Date Issued: 4/25/07 — License Reviewer: LL

File No.: 25
Licensee: Univ. CA Irvine Medical Center — License No.: 0278
Type of Action: Amendment — Amendment No.: 163
Date Issued: 1/29/08 — License Reviewer: HA

File No.: 26
Licensee: ABC Management, Inc. — License No.: 4755
Type of Action: Termination — Amendment No.: 30
Date Issued: 6/1/07 — 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 — License No.: 0764
Date of Incident: 5/24/06 — NMED Log No.: 060399
Investigation Date: 5/26/06 — Type of Incident: Lost/Stolen Material
Type of Investigation: Site

File No.: 2
Licensee: North Oaks Radiation Center — License No.: 3693
Date of Incident: 8/9/06 — NMED Log No.: 060515
Investigation Date: 8/14/06 — 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 — License No.: N/A
Date of Incident: 8/29/06 — NMED Log No.: 060555
Investigation Date: 8/30/06 — Type of Incident: Lost/Stolen Material
Type of Investigation: Site

File No.: 4
Licensee: Schlumberger Technology — License No.: 0144
Date of Incident: 10/4/06 — NMED Log No.: 060633
Investigation Date: 10/7/06 — Type of Incident: Contamination/Leaking Source
Type of Investigation: Site

File No.: 5
Licensee: California State Polytechnic University — License No.: 0496
Date of Incident: 10/06 — NMED Log No.: 060752
Investigation Date: 12/6/06 — Type of Incident: Lost/Stolen Material
Type of Investigation: Site

File No.: 6
Licensee: Smith-Emery Co. — License No.: 2878
Date of Incident: 3/2/07 — NMED Log No.: 070133
Investigation Date: 3/2/07 — Type of Incident: Damaged Equipment
Type of Investigation: Telephone

File No.: 7
Licensee: Leland Stanford, Jr., University License No.: 0676
Date of Incident: 3/5-9/07 NMED Log No.: 070216
Investigation Date: 3/14/07 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 License No.: 6833
Date of Incident: 3/19/07 NMED Log No.: 070180
Investigation Date: 4/6/07 Type of Incident: Medical
Type of Investigation: Telephone

File No.: 9
Licensee: Good Samaritan Hospital License No.: 1731
Date of Incident: 8/14/06 NMED Log No.: 060527
Investigation Date: 8/16/06 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 License No.: 0404
Date of Incident: 1/17/07 NMED Log No.: 070089
Investigation Date: 1/18/07 Type of Incident: Loss of Control
Type of Investigation: Site

File No.: 11
Licensee: Converse Consultants License No.: 4057
Date of Incident: 5/22/07 NMED Log No.: 070316
Investigation Date: 5/22/07 Type of Incident: Lost/Stolen Material
Type of Investigation: Site

File No.: 12
Licensee: Chapman Medical Center, Inc. License No.: 1946
Date of Incident: 10/10/06 NMED Log No.: 060634
Investigation Date: 10/10/06 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. License No.: 1053
Date of Incident: 8/2/04 Incident Log No.: Book 2/#4
Investigation Date: 10/28/04 Type of Incident: Interlock failure
Type of Investigation: Technical review

File No.: 5
Licensee: Ancore Corp. License No.: 2484
Date of Incident: 12/23/03 Incident Log No.: Book 2/#5
Investigation Date: 10/13/04 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 License No.: 1335
Date of Incident: 1/26/06 Incident Log No.: Book 2/#6
Investigation Date: 1/27/06 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 License No.: 1731
Date of Incident: 8/16/06 Incident Log No.: Book 2/#7
Investigation Date: 1/4/07 Type of Incident: Stuck source
Type of Investigation: Technical review

File No.: 8
Licensee: Decisive Testing Co. License No.: 1836
Date of Incident: 3/5/04 Incident Log No.: Book 2/#8
Investigation Date: 3/11/04 Type of Incident: Source disconnect
Type of Investigation: Inspection

File No.: 9
Licensee: City of Hope/Beckman Research Institute License No.: 0307
Date of Incident: 7/16/07 Incident Log No.: Book 2/#9
Investigation Date: 12/27/07 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 — SS&D Type: (V) General Medical Use
Applicant Name: Radiance Medical Systems, Inc. — Type of Action: Inactivation
Date Issued: 7/11/07 — 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 — SS&D Type: (H) General Neutron Source
Applicant Name: Thermo Gamma Metrix, Inc. — Type of Action: Amendment
Date Issued: 8/17/07 — SS&D Reviewers: ZG, RR

File No.: 3
Registry No.: CA-0309-D-103-G — SS&D Type: (D) Gamma Gauge
Applicant Name: General Atomics — Type of Action: New Registration
Date Issued: 11/6/07 — 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 — SS&D Type: (F) Well-logging Source
Applicant Name: Eckert & Ziegler Isotope Products — Type of Action: Amendment
Date Issued: 12/5/07 — 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 SS&D Type: (D) Gamma Gauge
Applicant Name: Science Applications, Inc. Type of Action: Amendment
Date Issued: 1/10/08 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 SS&D Type: (H) General Neutron Source
Applicant Name: Thermo Gamma Metrix, Inc. Type of Action: Amendment
Date Issued: 10/22/07 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 SS&D Type: (S) Foil Source
Applicant Name: Eckert & Ziegler Isotope Products Type of Action: Amendment
Date Issued: 1/31/08 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 SS&D Type: (U) X-ray Fluorescence
Applicant Name: Eckert & Ziegler Isotope Products Type of Action: New Registration
Date Issued: 7/27/04 SS&D Reviewers: HA, JF

File No.: 9
Registry No.: CA-0598-D-115-S SS&D Type: (K) Gamma Irradiator
Applicant Name: J. L. Shepherd and Associates Type of Action: Amendment
Date Issued: 8/20/04 SS&D Reviewers: JF, HA

File No.: 10
Registry No.: CA-0380-D-101-S SS&D Type: (H) General Neutron Source
Applicant Name: Nova R&D, Inc. Type of Action: Amendment
Date Issued: 9/4/04 SS&D Reviewers: FM, JF

File No.: 11
Registry No.: CA-0102-D104-S SS&D Type: (Y) Calibration
Applicant Name: ADAC Laboratories, Inc. Type of Action: Amendment
Date Issued: 11/24/04 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 SS&D Type: (Y) Calibrator
Applicant Name: ADAC Laboratories, Inc. Type of Action: New Registration
Date Issued: 12/22/04 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 SS&D Type: (D) Gamma Gauge
Applicant Name: Belden Engineering Type of Action: New Registration
Date Issued: 4/7/05 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 SS&D Type: (D) Gamma Gauge
Applicant Name: Belden Engineering Type of Action: New Registration
Date Issued: 4/11/05 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 SS&D Type: (X) Medical Reference Source
Applicant Name: Eckert & Ziegler Isotope Products Type of Action: New Registration
Date Issued: 7/11/07 SS&D Reviewers: FM, HA

File No.: 16
Registry No.: CA-1046-D-102-S SS&D Type: (H) General Neutron Source
Applicant Name: Analyser Systems, Inc. Type of Action: New Registration
Date Issued: 2/28/06 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 SS&D Type: (U) X-Ray Fluorescence
Applicant Name: Thermo Electron Corp. Type of Action: New Registration
Date Issued: 5/3/06 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 SS&D Type: (J) Gamma Irradiator
Applicant Name: J. L. Shepherd and Associates Type of Action: Amendment
Date Issued: 5/25/06 SS&D Reviewers: NG, JF

File No.: 19
Registry No.: CA-0406-D-107-S SS&D Type: (X) Medical Reference Source
Applicant Name: Isotope Product Labs. Type of Action: Amendment
Date Issued: 7/14/06 SS&D Reviewers: BB, JF

File No.: 20
Registry No.: CA-1259-D-101-S SS&D Type: (H) General Neutron Source
Applicant Name: HiEnergy Technologies, Inc. Type of Action: New Registration
Date Issued: 9/29/06 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 SS&D Type: (AA) Manual Brachytherapy
Applicant Name: North American Scientific Type of Action: New Registration
Date Issued: 7/2/07 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